UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
SOUTHERN DIVISION

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| UNITED STATES OF AMERICA, *ex rel.* C. DUSTIN BECHTOLD, M.D. AND BRYAN WELLMAN, M.D.,<br><br>Plaintiff/Relators,<br><br>v.<br><br>WILSON ASFORA, M.D., MEDICAL DESIGNS, LLC, and SICAGE, LLC,<br><br>Defendants. | **COMPLAINT**<br><br>CIV. 16-4115-LLP<br><br>JURY TRIAL<br><br>DEMANDED<br><br>**REDACTED VERSION** |

The United States of America, for its complaint, states:

## NATURE OF ACTION

1. This is an action to recover damages and civil penalties under the False Claims Act (FCA), 31 U.S.C. §§ 3729–33, and to recover money for common law or equitable causes of action for payment by mistake and unjust enrichment. The United States' claims arise out of defendants' illegal scheme to knowingly submit, and cause to be submitted, claims to federal healthcare programs for items and services that resulted from kickbacks, were not medically necessary, and were otherwise false and fraudulent.

2. From June 2011 through December 2018, defendant Wilson Asfora, M.D. (Asfora) engaged in multiple kickback schemes with defendants Medical Designs, LLC (MDLLC), Sicage, LLC (Sicage), and others designed to pay Asfora hundreds of thousands of dollars in exchange for his use of medical devices and other products in his spinal surgeries. These kickback schemes violated the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b), resulted in medically

unnecessary surgical procedures, and caused the submission of false claims to Medicare, Medicaid, and TRICARE in violation of the FCA.

3. First, MDLLC paid profit distributions to Asfora and his wife that were based on and resulted from Asfora's use of MDLLC devices. Asfora, a physician-owner of MDLLC, was the only physician to regularly use MDLLC's spinal fusion devices during the relevant period. The MDLLC devices were substantially equivalent to other commercially-available devices, were not unique or superior, and were used by Asfora at Sioux Falls Specialty Hospital (SFSH) and Sanford Medical Center (SMC) (collectively, "the Hospitals") to make money.

4. Second, MDLLC sought and received from multiple device companies a valuable license to purchase the companies' spinal devices and resell the devices at a substantial profit when Asfora used the devices at the Hospitals. MDLLC did not invent, design, manufacture, advertise, sterilize, or package any of the devices, and it did not have any personnel to market the devices. MDLLC simply purchased and resold the devices for its physician-owner's use. Through this arrangement, MDLLC received a portion of the profits that the device companies otherwise would have received from the sale of the devices, and MDLLC paid the resulting profit distributions to Asfora and his wife.

5. Third, MDLLC covertly sold a sacroiliac device to SFSH for Asfora's use, so that MDLLC and its physician-owner Asfora could capture the profits each time Asfora used the device. Although another company—Blackstone Medical, Inc. d/b/a Orthofix Spinal Implants (Orthofix)—held the exclusive license to make and distribute the sacroiliac device, MDLLC and Asfora repeatedly asked Orthofix to pay MDLLC based on Asfora's use of the device or to allow MDLLC to sell (and profit from the sale of) the device when Asfora used it. Orthofix rejected MDLLC's and Asfora's demands and warned them that their request was "illegal." Undeterred,

MDLLC sold the sacroiliac device at a substantial markup to SFSH for Asfora's use, paid the profits to Asfora, and concealed the unauthorized sales from Orthofix.

6. Fourth, in order to profit from Asfora's use of sacroiliac devices at SMC, Asfora and MDLLC employees created a new company, Sicage, to distribute a sacroiliac device substantially equivalent to the device that Orthofix exclusively licensed. Sicage sold those devices only to Sanford Health and only for Asfora's use at SMC. Sicage offered, and Asfora solicited, profit distributions based on Asfora's use of Sicage devices. Sicage's device was neither unique nor superior to other commercially-available devices, and was used by Asfora to make money.

7. Asfora and MDLLC knew of the AKS and FCA, understood the AKS's prohibition on offering or paying money to induce referrals and the FCA's prohibition on submitting or causing to be submitted claims resulting from kickbacks, and had previously settled separate FCA and AKS allegations with the United States in 2013. Nevertheless, Asfora and MDLLC engaged in numerous illegal kickback schemes, created a new company—Sicage—to use in another kickback scheme, and disregarded numerous warnings, including from their own attorney, that their conduct was illegal. Asfora also received numerous warnings that he was performing medically unnecessary procedures—which were "excessive," "quite aggressive[]," and went "against conventional neurosurgical teaching and practice"—with the devices in which he had a financial interest. However, Asfora continued to submit, and caused the Hospitals to submit, claims to federal healthcare programs for surgeries resulting from the kickbacks, including unnecessary procedures.

## JURISDICTION AND VENUE

8. This action arises under the FCA and the common law.

9. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1345 because the United States is the plaintiff. The Court also has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1367(a).

10. The Court may exercise personal jurisdiction over the defendants under 31 U.S.C. § 3732(a) because the defendants can be found, reside, and transact business in this District.

11. Venue is proper in the District of South Dakota under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) because the defendants can be found, reside, and transact business in this District; and many of the events giving rise to these claims occurred in this District.

## PARTIES

12. Plaintiff, the United States of America, acting through the Department of Health and Human Services (HHS), administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act (SSA), 42 U.S.C. §§ 1395 *et seq.* (Medicare). The United States, acting through the Defense Health Agency (DHA), administers the TRICARE program (formerly CHAMPUS). Relators Carl Dustin Bechtold, M.D. (Bechtold) and Bryan Wellman, M.D. (Wellman) have filed this case under the FCA's *qui tam* provisions, and the United States has intervened.

13. Relator Bechtold is an orthopedic surgeon who has been employed by Sanford Clinic since at least 2010 to provide medical services, including surgeries, to patients at SMC. Bechtold is board-certified by the American Board of Orthopedic Surgery and was licensed by the State of South Dakota as a physician at all times relevant to this Complaint.

14. Relator Wellman is a neurosurgeon who has been employed by Sanford Clinic since at least 2010 to provide medical services, including surgeries, to patients at SMC. Wellman is board-certified by the National Board of Medical Examiners and the American Board of

Neurological surgeons and was licensed by the State of South Dakota as a physician at all times relevant to this Complaint.

15. Defendant Asfora, a neurosurgeon, resides in Sioux Falls, South Dakota and has maintained a residence and office in Sioux Falls, South Dakota since at least 2010. During the relevant time period, Asfora provided medical services, including surgeries, to patients at the Hospitals. Since at least 2010, Asfora has submitted claims to, and received reimbursement from, federal healthcare programs for his medical services. Asfora was licensed by the State of South Dakota as a physician at all times relevant to this Complaint.

16. Defendant MDLLC was organized, and exists, as a privately-held South Dakota limited liability company pursuant to the South Dakota Limited Liability Company (LLC) Act. MDLLC's principal office is located at 6709 S. Minnesota Avenue, Suite 204, Sioux Falls, South Dakota. Since at least 2010, Asfora and his wife have been the only owners of MDLLC, with each owning 50% of the company. Since at least 2010, MDLLC has derived most of its revenue from the sale of medical devices to the Hospitals for Asfora's use. From 2012 to 2018, MDLLC had two employees, Kristi Vondra, MDLLC's Vice President of Operations, and Kelly Spielman, MDLLC's Quality System Assistant.

17. Defendant Sicage was organized, and exists, as a privately-held South Dakota limited liability company pursuant to the South Dakota LLC Act. Sicage's principal office is located at 6709 S. Minnesota Avenue, Suite 206, Sioux Falls, South Dakota. In 2017 and 2018, Asfora was the sole owner of Sicage, and Sicage derived all of its revenue from the sale of medical devices to Sanford Health for Asfora's use at SMC. Sicage has had two employees, Kristi Vondra, Sicage's Vice President of Operations, and Kelly Spielman, Sicage's Quality System Assistant.

## LEGAL AND REGULATORY BACKGROUND

### I. THE FALSE CLAIMS ACT

18. The FCA provides, in pertinent part, that any person who:

> (a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (a)(1)(C) conspires to commit a violation of subparagraph (A) [or] (B) . . .

is liable to the United States for three times the amount of damages which the Government sustains, plus a civil penalty per violation. For violations occurring between September 28, 1999 and November 1, 2015, the civil penalty amounts range from a minimum of $5,500 to a maximum of $11,000. *See* 28 C.F.R. § 85.3; 64 Fed. Reg. 47099, 47103 (1999). For violations occurring on or after November 2, 2015, the civil penalty amounts range from a minimum of $11,181 to a maximum of $22,363. 28 C.F.R. § 85.5.

19. For purposes of the False Claims Act,

> the terms "knowing" and "knowingly" (A) mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud. . . .

31 U.S.C. § 3729(b)(1).

20. The False Claims Act defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

### II. THE MEDICARE PROGRAM

21. In 1965, Congress enacted the Health Insurance for the Aged and Disabled Act, known as the Medicare program, to pay for the costs of certain healthcare services. 42 U.S.C.

§ 1395 *et seq.* Entitlement to Medicare benefits is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426 to 426-1.

22. HHS is responsible for administration and supervision of the Medicare program. The Centers for Medicare & Medicaid Services (CMS), an agency within HHS, is directly responsible for administering the Medicare program. For purposes of this action, there are two primary components to the Medicare program: Part A and Part B. Medicare Part A authorizes payment for institutional care, including inpatient hospital services. *See* 42 U.S.C. §§ 1395c to 1395i-5. Medicare Part B, a federally-subsidized, voluntary insurance program, covers a percentage of the fee schedule for physician services as well as a variety of "medical and other services." *See* 42 U.S.C. §§ 1395j to 1395w-5.

23. To participate in the Medicare program, a healthcare provider must file a provider agreement with the Secretary of HHS. 42 U.S.C. § 1395cc. The provider agreement requires compliance with the requirements that the Secretary deems necessary for participation in the Medicare program and in order to receive reimbursement from Medicare. The provider agreement specifically requires compliance with the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

24. To participate in the Medicare program as a new enrollee, institutional providers such as hospitals must submit a Medicare Enrollment Application, Form CMS-855A. These providers also must complete Form CMS-855A to change information or to reactivate, revalidate, and/or terminate Medicare enrollment.

25. Form CMS 855A requires, among other things, signatories to certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. . . . I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's

> compliance with all applicable conditions of participation in Medicare.
>
> * * *
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

*See* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855a.pdf (last visited Nov. 13, 2019).

26. An authorized official must sign the "Certification Section" in Section 15 of Form CMS-855A, which "legally and financially binds [the] provider to the laws, regulations, and program instructions of the Medicare program." *Id.*

27. In addition, within five months of the end of the cost reporting period, hospitals are required to submit to CMS annual reports known as "cost reports" on Form CMS-2552, *see* 42 C.F.R. §§ 413.20(b), 413.24(f)(2). Part II of Form CMS-2552 and 42 C.F.R. § 413.24(f)(4)(iv)(B) require a mandatory certification, which includes the following certification statement:

> MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED IN THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND OR IMPRISONMENT MAY RESULT.

https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3P240f.pdf (last visited Nov. 13, 2019).

28. Form CMS-2552 and 42 C.F.R. § 413.24(f)(4)(iv)(B) require a chief financial officer or administrator of the hospital to certify that "I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report

and the Balance Sheet and Statement of Revenue and Expenses prepared by [Provider Name(s) and Number(s)] for the cost reporting period beginning [date] and ending [date] and to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted." *Id.*

29. Form CMS-2552 and 42 C.F.R. § 413.24(f)(4)(iv)(B) also require a chief financial officer or administrator of the hospital to certify that "I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations." *Id.*

30. To participate in the Medicare program as a new enrollee, physicians must submit a Medicare Enrollment Application, Form CMS-855I. These providers also must complete Form CMS-855I to change information or to reactivate, revalidate, and/or terminate Medicare enrollment.

31. Form CMS-855I requires, among other things, signatories to certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in section 4A of this application. The Medicare laws, regulations, and program instructions are available through the Medicare Administrative Contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b) . . . .
>
> * * *
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

*See* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855i.pdf (last visited Nov. 13, 2019).

32. The provider must sign the "Certification Section" in Section 15 of Form CMS-855I, and in doing so, is "attesting to meeting and maintaining the Medicare requirements" excerpted above, among others. *Id.*

33. Medicare reimburses only those services furnished to beneficiaries that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ." 42 U.S.C. § 1395y(a)(l)(A).

34. The Secretary of HHS (Secretary) is responsible for specifying services covered under the "reasonable and necessary" standard and has wide discretion in selecting the means for doing so. *See* 42 U.S.C. § 1395ff(a). The Secretary acts through formal regulations, and periodically CMS and HHS-OIG issue industry guidance.

35. The Secretary provides guidance to eligible providers pursuant to a series of Manuals, published by CMS, which are available to the public on the Internet. *See generally* CMS Internet-Only Manuals, *available at* https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms.html (last visited Nov. 13, 2019).

36. At all times relevant to this Complaint, CMS contracted with private contractors, known as Medicare Administrative Contractors (MACs), to perform various administrative functions on its behalf, including reviewing and paying claims submitted by healthcare providers. 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104. MACs generally act on behalf of CMS to process and pay Medicare claims and perform administrative functions on a regional level. MACs may issue Local Coverage Determinations regarding whether or not a particular item or service is covered. 42 U.S.C. § 1395ff(f)(2).

37. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R.

§ 424.516(a)(1). In submitting claims for payment to Medicare, providers must certify that the information on the claim form accurately describes the services rendered and that the services were reasonable and medically necessary for the patient.

38. In each of the claims at issue in this action, Asfora, SFSH, and/or SMC certified to CMS that the services were reasonable and medically necessary for the patient.

**A. Medicare Part A**

39. Under Medicare Part A, hospitals agree with Medicare to provide covered healthcare items and services to treat Medicare patients. The hospital, also called a "provider," is authorized to bill Medicare for that treatment. During the relevant time period, CMS reimbursed hospitals for inpatient Part A services through MACs (formerly known as fiscal intermediaries).

40. Since 2007, in order to get paid, a hospital must complete and submit to the MAC a claim for payment on a Form UB-04, also known as CMS-1450. This form contains patient-specific information including the diagnosis and types of services that are assigned or provided to the Medicare patient. The Medicare program relies on the accuracy and truthfulness of the UB-04 Forms to determine whether the service is payable and what amounts the hospital is owed.

41. In addition, as noted previously, hospitals are required to submit to the MAC an annual report known as a Medicare "cost report" on Form CMS-2552, which identifies any outstanding costs that the hospital is claiming for reimbursement for that year. The cost report serves as the final claim for payment that is submitted to Medicare. The Medicare program relies on the accuracy and truthfulness of the cost report to determine what amounts, if any, the hospital is owed or has been overpaid during the year.

42. In 1983, Congress established the prospective payment system (PPS) as the system by which hospitals are reimbursed for inpatient hospital costs. Under PPS, the amount Medicare

pays a hospital for treating an inpatient Medicare beneficiary is largely based on the condition that led to the patient's admission to, or that was principally treated by, the hospital.

43. Payments made under PPS "are payment in full for all inpatient hospital services," 42 C.F.R. § 412.50(a), including the "[d]rugs, biologicals, supplies, appliances, and equipment" furnished to an inpatient. *Id.* § 409.10(a)(5). Such supplies, appliances, and equipment include "item[s] . . . that the beneficiary must continue to use after he or she leaves the hospital[,]" including implanted spinal devices. *Id.* § 409.14(b)(1).

44. Under PPS, a patient's condition or treatment is categorized under a classification system called a diagnosis related group (DRG). DRG classifications and payment rates are created by CMS based on the aggregation of weighted factors and average costs over time. *See* 42 C.F.R. § 412.60. The DRG establishes how much the hospital will be paid under Medicare and reflects the resources that the patient's condition or treatment typically requires. The DRG reimburses the hospital for the expected costs of any items that it must purchase in connection with the hospitalization, including medical devices, where those devices are appropriately used to treat a Medicare beneficiary.

45. The patient-specific information (e.g., the diagnosis codes) submitted by the hospital on the Form UB-04 is used to determine what DRG is assigned to a certain claim, and hence, what amount will be paid to the hospital.

**B. Medicare Part B**

46. Medicare Part B is funded by insurance premiums paid by enrolled Medicare beneficiaries and by contributions from the Federal Treasury. Eligible individuals who are 65 or older, or disabled, may enroll in Medicare Part B to obtain benefits in return for payments of monthly premiums. Payments under Medicare Part B typically are made directly under assignment

to service providers and practitioners, such as physicians, rather than to the patient/beneficiary. In that case, the physician bills the Medicare program directly.

47. The United States provides reimbursement for Medicare Part B claims from the Medicare Trust Fund through CMS. To assist in the administration of Medicare Part B, CMS contracts with MACs (formerly known as carriers). 42 U.S.C. § 1395u. MACs are responsible for performing a host of administrative functions on CMS' behalf, including processing the payment of Medicare Part B claims to providers.

48. To bill Medicare, a physician must submit an electronic or hard-copy CMS-1500 claim form to the MAC. When the CMS-1500 claim is submitted, the physician certifies that he or she is knowledgeable of Medicare's requirements and that the services for which payment is sought were "medically indicated and necessary for the health of the patient."

49. Physicians wishing to submit an electronic or hard-copy CMS-1500 claim must first seek to enroll in the Medicare program by submitting a provider enrollment form. During the Medicare enrollment process, providers must agree to certify that the claims they submit will be "accurate, complete, and truthful."

50. For a CMS-1500 claim to be paid by Medicare Part B, it must identify each service rendered to the patient by the physician. The service is identified through a corresponding code that is listed in the American Medical Association (AMA) publication called the Current Procedural Terminology (CPT) Manual. The CPT is a systematic list of codes for procedures and services performed by or at the direction of a physician. Each procedure or service is identified by a five-digit CPT code.

51. In addition to the CPT Manual, the AMA publishes the International Classification of Diseases (ICD) Manual, which assigns a unique numeric identifier to each medical condition.

In order to be payable by Medicare, the CMS-1500 claim must identify both the CPT code that the provider is billing for and the corresponding ICD code that identifies the patient's medical condition that renders the provider's service medically necessary.

52. When submitting claims to Medicare, providers certify on the CMS-1500, among other things, that: (a) the services rendered are medically indicated and necessary for the health of the patient; (b) the information in the claim is "true, accurate, and complete"; and (c) the provider understands that "payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of material fact, may be prosecuted under applicable Federal and State laws." After a February 2012 revision to the CMS-1500, providers further certify that their claims comply "with all applicable Medicare . . . laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute . . . ." CMS-1500 also requires providers to acknowledge that: "Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties."

53. Healthcare providers are prohibited from knowingly presenting or causing to be presented claims for items or services that the person knew or should have known were not medically necessary, or knew or should have known were false or fraudulent. *E.g.*, 42 U.S.C. §§ 1320a-7a(a)(1) (civil monetary penalties), 1320a-7(b)(7) (permitting exclusion of providers for fraud, kickbacks, and other prohibited activities).

54. A provider has a duty to familiarize itself with the statutes, regulations, and guidelines regarding coverage for the Medicare services it provides. *Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 64 (1984).

55. Because it is not feasible for the Medicare program or its contractors to review medical records corresponding to each of the millions of claims for payment it receives from providers, the program relies on providers to comply with Medicare requirements and relies on providers to submit truthful and accurate certifications and claims.

56. Generally, once a provider submits a CMS-1500 or the electronic equivalent to the Medicare program, the claim is paid directly to the provider, in reliance on the foregoing certifications, without any review of supporting documentation, including medical records.

## III. STATE MEDICAID PROGRAMS

57. State Medicaid programs are authorized by Title XIX of the Social Security Act. 42 U.S.C. §§ 1396 *et seq.* Medicaid is a joint federal-state program that provides healthcare benefits for certain groups including the poor and disabled. Each state Medicaid program is required to implement a "State Plan" containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. § 1396a.

58. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage (FMAP), is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). During the relevant time period, the federal portion of Medicaid payments was as follows for the states of South Dakota, Iowa, and Minnesota:

| Time Period | SD | IA | MN |
|---|---|---|---|
| 4/1/11 - 6/30/11 | 63.92% | 64.71% | 51.20% |
| 7/1/11 - 9/30/11 | 61.25% | 62.63% | 50.00% |
| 10/1/11 - 9/30/12 | 59.13% | 60.71% | 50.00% |
| 10/1/12 - 9/30/13 | 56.19% | 59.59% | 50.00% |
| 10/1/13 - 9/30/14 | 53.54% | 57.93% | 50.00% |
| 10/1/14 - 9/30/15 | 51.64% | 55.54% | 50.00% |
| 10/1/15 - 9/30/16 | 51.61% | 54.91% | 50.00% |

| Time Period | SD | IA | MN |
|---|---|---|---|
| 10/1/16 - 9/30/17 | 54.94% | 56.74% | 50.00% |
| 10/1/17 - 9/30/18 | 55.34% | 58.48% | 50.00% |
| 10/1/18 - 9/30/19 | 56.71% | 59.93% | 50.00% |

*See* 76 Fed. Reg. 32,204, 32,207 (June 3, 2011) (Q3 FY 2011); 74 Fed. Reg. 62,315, 62,316–17 (Nov. 27, 2009) (Q4 FY 2011); 75 Fed. Reg. 69,082, 69,083 (Nov. 10, 2010) (FY 2012); 76 Fed. Reg. 74,061, 74,062–63 (Nov. 30, 2011) (FY 2013); 77 Fed. Reg. 71,420, 71,422 (Nov. 30, 2012) (FY 2014); 79 Fed. Reg. 3385, 3387 (Jan. 21, 2014) (FY 2015); 79 Fed. Reg. 71,426, 71,428 (Dec. 2, 2014) (FY 2016); 80 Fed. Reg. 73,779, 73,781–82 (Nov. 25, 2015) (FY 2017); 81 Fed. Reg. 80,078, 80,080 (Nov. 15, 2016) (FY 2018); 82 Fed. Reg. 55,383, 55,385 (Nov. 21, 2017) (FY 2019).

**A. South Dakota Medicaid Program**

59. Pursuant to 42 C.F.R. § 431.18, the South Dakota Department of Social Services (DSS) has issued South Dakota Medicaid Provider Manuals for the purpose of furnishing Medicaid providers with the policies and procedures needed to receive reimbursement for covered services provided to eligible South Dakota Medicaid recipients. Throughout the relevant time period, the South Dakota Medicaid Provider Manuals were available for review at the State office and in each local and district office, as well as online at https://dss.sd.gov/medicaid/providers (last visited Nov. 13, 2019).

60. To participate in the South Dakota Medicaid program, providers such as physicians and hospitals must certify in their state Medicaid provider agreement that they will "comply with all Federal and State laws, regulations and rules applicable to Provider's participation in the SD Medicaid Program." *See* https://dss.sd.gov/docs/medicaid/providers/provider_agreement.pdf (last visited Nov. 13, 2019). Further, providers must "declare and affirm under the penalties of perjury

that any claim to be submitted pursuant to this Agreement will be examined by me, and to the best of my knowledge and belief, will be in all things true and correct." *Id.*

61. The South Dakota Medicaid provider agreement also requires the provider to "agree[] to provide medically necessary goods and services as required by the recipient and only in the amount required by the recipient . . . ." *Id.* Participating providers must "acknowledge[] that by submitting a claim to the SD Medicaid Program, Provider certifies that the services and supplies were . . . [m]edically necessary . . . ." Further, the Provider must "agree[] to submit claims . . . [i]n accordance with billing manuals and instructions, Companion Guides, and as required under any and all state regulations; [and] [t]hat are timely, true, accurate, and complete . . . ." *Id.*

62. The South Dakota Medicaid provider agreement also requires participating providers to "acknowledge[] by Provider's signature on this Agreement that Provider understands that payment and satisfaction of each claim will be from Federal and State funds and that any false claims, statements or documents, or concealment of material fact, may be prosecuted under applicable Federal and State law." *Id.*

63. State regulations promulgating the South Dakota Medicaid program rules specifically require that physician and hospital services "must be medically necessary" to be covered by the Medicaid program. S.D. Admin. R. § 67:16:01:06.02.

64. A physician enrolled as a South Dakota Medicaid provider must submit claims on a CMS-1500 claim form, which contains the certifications specified above in Section II.B. A hospital enrolled as a South Dakota Medicaid provider must submit claims on a UB-04 claim form, which contains the certifications specified above in Section II.A.

65. Because it is not feasible for the South Dakota Medicaid program or its contractors to review medical records corresponding to each of the claims for payment it receives from

providers, the program relies on providers to comply with Medicaid requirements and relies on providers to submit truthful and accurate certifications and claims.

**B. Iowa Medicaid Program**

66. Pursuant to 42 C.F.R. § 431.18, the Iowa Department of Human Services has issued Iowa Medicaid Provider Manuals for the purpose of furnishing Medicaid providers with the policies and procedures needed to receive reimbursement for covered services provided to eligible Iowa Medicaid recipients. Throughout the relevant time period, the Iowa Medicaid Provider Manuals were available for review at the State office and in each local and district office, as well as online at https://dhs.iowa.gov/policy-manuals/medicaid-provider (last visited Nov. 13, 2019).

67. To participate in the Iowa Medicaid program, providers such as physicians and hospitals must certify in their state Medicaid enrollment application that they "understand that payment of claims will be from federal and state funds and that any falsification or concealment of a material fact may be prosecuted under federal and state law." (Form 470-0254.)

68. Further, in Iowa's Medicaid provider agreement, providers must agree to "[c]omply with all applicable Federal and State laws, administrative rules and written policies of the Iowa Medicaid program, including but not limited to Title XIX of the Social Security Act (as amended), the Code of Federal Regulations, the Federal anti-kickback statute and the Stark law, the provisions of the Code of Iowa and administrative rules of the Iowa Department of Human Services and written Department policies, including but not limited to, policies contained in the Iowa Medicaid Provider Manual, and the terms of this Agreement." (Form 470-2965.)

69. Further, providers acknowledge that Iowa's Medicaid program pays for only "medically necessary goods and/or services actually and properly provided" to Iowa Medicaid beneficiaries. (Form 470-2965.)

70. State regulations promulgating the Iowa Medicaid program rules specifically require that physician and hospital services must be "medically necessary" to be covered by the Medicaid program. *See* 41 Iowa Admin. Code § 78.

71. A physician enrolled as an Iowa Medicaid provider must submit claims on a CMS-1500 claim form, which contains the certifications specified above in Section II.B. A hospital enrolled as an Iowa Medicaid provider must submit claims on a UB-04 claim form, which contains the certifications specified above in Section II.A.

72. Because it is not feasible for the Iowa Medicaid program or its contractors to review medical records corresponding to each of the claims for payment it receives from providers, the program relies on providers to comply with Medicaid requirements and relies on providers to submit truthful and accurate certifications and claims.

**C. Minnesota Medicaid Program**

73. Pursuant to 42 C.F.R. § 431.18, the Minnesota Department of Human Services has issued Minnesota Medicaid Provider Manuals for the purpose of furnishing Medicaid providers with the policies and procedures needed to receive reimbursement for covered services provided to eligible Minnesota Medicaid recipients. Throughout the relevant time period, the Minnesota Medicaid Provider Manuals were available for review at the State office and in each local and district office, as well as online at https://mn.gov/dhs/partners-and-providers/edocs (last visited Nov. 13, 2019).

74. To participate in the Minnesota Medicaid program, providers such as physicians and hospitals must certify in their state Medicaid provider agreement that they will "[c]omply with all federal and state statutes and rules relating to the delivery of services to individuals and to the submission of claims for such services." (Form DHS-4138.)

75. Further, a participating provider must "[a]ssume full responsibility for the accuracy of claims submitted to [the Minnesota Medicaid program] in accordance with the certification requirements of 42 C.F.R. § 455.18 and Minnesota Statutes 256B.27, subd. 2." (Form DHS-4138.) Pursuant to those certification requirements, the provider must certify, among other things, that each claim submitted is "true, accurate, and complete" and that the provider "understand[s] that payment of this claim will be from Federal and State funds, and that any falsification, or concealment of a material fact, may be prosecuted under Federal and State laws." *Id.*

76. The Minnesota Medicaid provider agreement also requires the provider to agree to "submit claims only for services, supplies, and equipment that are medically necessary as defined at Minnesota Rules 9505.0175, subp. 25, and that meet professionally recognized standards of health care, [and] that Provider knows or has reason to know are properly reimbursable under federal and state statutes and rules." (Form DHS-4138.)

77. State regulations promulgating the Minnesota Medicaid program rules specifically require that physician and hospital services must be, among other things, "medically necessary," "appropriate and effective for the medical needs of the recipient," and "the most cost-effective health service available for the medical needs of the recipient" to be covered by the Medicaid program. Minn. Admin. R. 9505.0210.

78. A physician enrolled as a Minnesota Medicaid provider must submit claims on a CMS-1500 claim form, which contains the certifications specified above in Section II.B. A hospital enrolled as a Minnesota Medicaid provider must submit claims on a UB-04 claim form, which contains the certifications specified above in Section II.A.

79. Because it is not feasible for the Minnesota Medicaid program or its contractors to review medical records corresponding to each of the claims for payment it receives from providers,

the program relies on providers to comply with Medicaid requirements and relies on providers to submit truthful and accurate certifications and claims.

## IV. THE TRICARE PROGRAM

80. TRICARE (formerly CHAMPUS) is a medical benefits program established by federal law. 10 U.S.C. §§ 1071–1110b. TRICARE covers eligible beneficiaries, including active duty members of the Uniformed Services and their dependents as well as retired members of the Uniformed Services and their dependents. The federal government reimburses a portion of the cost of healthcare services and prescription medications provided to TRICARE beneficiaries. TRICARE is administered by the DHA.

81. TRICARE covers only medically necessary inpatient and outpatient care. TRICARE defines medically necessary care as services or supplies provided by a hospital, physician, and/or other provider for the prevention, diagnosis, and treatment of an illness, when those services or supplies are determined to be consistent with the condition, illness, or injury; are provided in accordance with approved and generally accepted medical or surgical practice; are not primarily for the convenience of the patient, the physician, or other providers; and do not exceed (in duration or intensity) the level of care which is needed to provide safe, adequate, and appropriate diagnosis and treatments. *See* 32 C.F.R. § 199.4(a)(1)(i) and applicable definitions at 32 C.F.R. § 199.2.

82. TRICARE regulations also provide that TRICARE may deny payment in "abuse situations." 32 C.F.R. § 199.9(b). To avoid abuse situations, providers are obligated to provide services and supplies under TRICARE that are: "Furnished at the appropriate level and only when and to the extent medically necessary . . .; of a quality that meets professionally recognized standards of health care; and, supported by adequate medical documentation as may reasonably be

required under this part . . . to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of care." *Id.*

83. TRICARE regulations, in turn, define "appropriate" medical care as that which is, among other things, "[f]urnished economically"—i.e., "in the least expensive level of care or medical environment adequate to provide the required medical care." 32 C.F.R. § 199.2.

84. As with Medicare, providers submit claims to TRICARE using the CMS-1500 or an electronic equivalent. Providers therefore make the same certifications in submitting claims to TRICARE as they do when submitting claims to Medicare.

85. Because it is not feasible for the TRICARE program or its contractors to review medical records corresponding to each of the claims for payment it receives from providers, the program relies on providers to comply with TRICARE requirements and submit truthful and accurate certifications and claims.

## V. THE ANTI-KICKBACK STATUTE

86. The Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b), arose out of Congressional concerns involving physicians' conflicts of interest and overutilization of medical services and items. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, § 242(b), (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93. The AKS prohibits the payment of kickbacks in order to protect the integrity of federal healthcare programs such as Medicare, Medicaid, and TRICARE.

87. The AKS prohibits any person from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward a person for, *inter alia*, purchasing, ordering, arranging for, or recommending the purchase or ordering of any goods or services for which payment may be made, in whole or in part, under a federal healthcare program.

88. In pertinent part, the AKS provides:

> b. Illegal remunerations
>
> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than ten years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than ten years, or both.

42 U.S.C. § 1320a-7b(b). "[A] person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]." *Id.* § 1320a-7b(h).

89. Pursuant to the AKS, "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g); *see also, e.g.*, *Guilfoile v. Shields*, 913 F.3d 178, 190–91 (1st Cir. 2019) ("§ 1320a-7b(g)'s obviation of the 'materiality' inquiry essentially codifies the long-standing view that AKS violations are 'material' in the FCA context.").

**A. AKS "Safe Harbors"**

90. The Office of Inspector General for HHS (OIG) has promulgated "safe harbor" regulations that define practices that are not subject to the AKS because such practices are unlikely to result in fraud or abuse. 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure persons involved of not being sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded to only those arrangements that meet all requirements of the safe harbor.

91. Under the investment interests safe harbor, a payment to an investor that is a return on an investment is not remuneration for purposes of the AKS only if all eight of the safe harbor's requirements are satisfied. *See* 42 C.F.R. § 1001.952(a).

92. The safe harbor for investment interests is narrowly tailored to prevent improper economic inducements from being disguised as ordinary investments. Among other things, the safe harbor for investment interests requires:

- The terms on which an investment interest is offered to an investor who is in a position to . . . generate business for the entity must not be related to the previous or expected volume of referrals . . . or the amount of business otherwise generated from that investor to the entity;
- No more than 40 percent of the entity's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12 month period may come from referrals or business otherwise generated from investors;

- No more than 40 percent of the value of the investment interests . . . may be held in the previous fiscal year or previous 12 month period by investors who are in a position to make or influence referrals to . . . or otherwise generate business for the entity; [and]

- The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

42 C.F.R. § 1001.952(a)(2)(i), (iii), (vi), (viii).

93. The direct and indirect payments from MDLLC to Asfora alleged herein did not satisfy the requirements of this or any other AKS safe harbor, and at all relevant times Asfora, MDLLC, and Sicage were aware that such payments did not satisfy any AKS safe harbor.

**B. OIG Special Fraud Alerts and Related Guidance**

94. To alert the public to "trends of health care fraud and certain practices of an industry-wide character," OIG issues special fraud alerts, which are published online and in the Federal Register. 59 Fed. Reg. 65,372, 65,373 (Dec. 19, 1994). The fraud alerts "provide general guidance to the health care industry" and assist others "in identifying health care fraud schemes." *Id.*

95. In 1989, OIG issued a Special Fraud Alert on Joint Venture Arrangements. OIG warned that physician joint venture arrangements may violate the AKS where the arrangement was "intended not so much to raise investment capital legitimately to start a business, but to lock up a stream of referrals from the physician investors and to compensate them indirectly for those referrals." OIG, Special Fraud Alert: Joint Venture Arrangements, *reprinted in* 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994).

96. OIG reiterated its concerns in a 2003 Special Advisory Bulletin regarding the "proliferation of arrangements between those in a position to refer business, such as physicians, and those providing items or services for which Medicare or Medicaid pays." OIG, Special

Advisory Bulletin: Contractual Joint Ventures, *reprinted in* 68 Fed. Reg. 23,148, 23,148 (Apr. 30, 2003) (warning that such "questionable contractual arrangements" may violate the AKS).

97. In March 2013, OIG issued another Special Fraud Alert regarding physician-owned entities, including such entities "referred to as physician-owned distributorships, or 'PODs.'" OIG Special Fraud Alert: Physician-Owned Entities (Mar. 26, 2013), *reprinted in* 78 Fed. Reg. 19,271, 19,272 (Mar. 29, 2013). OIG noted that it had previously warned that physician-owned medical device and distribution entities create "the strong potential for improper inducements" to physician-investors and "should be closely scrutinized under the fraud and abuse laws," including the AKS. *Id.* at 19,272 (quoting Letter from Vicki Robinson, "Response to Request for Guidance Regarding Certain Physician Investments in the Medical Device Industries" (Oct. 6, 2006)).

98. As OIG explained in its March 2013 Special Fraud Alert, PODs "derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers." *Id.*

99. The 2013 fraud alert reiterated longstanding AKS concerns regarding PODs, including: (1) the corruption of medical judgment, (2) overutilization, (3) increased costs to federal healthcare programs, and (4) unfair competition. *Id.* at 19,272.

100. The 2013 fraud alert warned that PODs are "inherently suspect" under the AKS, and it reiterated OIG's prior guidance that the opportunity for a referring physician to earn a profit, including through an investment return from an entity for which the physician generates business, could constitute illegal remuneration under the AKS. *Id.*

101. OIG identified the following five features, among others, that may render PODs particularly suspect under the AKS: (1) the POD "exclusively serves its physician-owners' patient

base," rather than selling "on the basis of referrals from nonowner physicians"; (2) the POD "generate[s] disproportionately high rates of return for physician-owners"; (3) the POD "enable[s] the physician-owners to profit from their ability to dictate the implantable devices to be purchased for their patients"; (4) the physician-owner(s) "are few in number, such that the volume or value of a particular physician-owner's recommendations or referrals closely correlates to that physician-owner's return on investment"; and (5) the physician-owner(s) "alter their medical practice after or shortly before investing in the POD (for example, by performing more surgeries, or more extensive surgeries, or by switching to using their PODs' devices on an exclusive, or nearly exclusive basis)." *Id.* at 19,273.

102. Each defendant was on notice of the foregoing Special Fraud Alerts and Bulletins, which were published in the Federal Register. In addition, each defendant received the March 2013 Special Fraud Alert and other documents containing the Alert's warnings about the requirements imposed by the AKS. For example, in June and July 2014, a newspaper in Sioux Falls published two articles about PODs operating at the Hospitals. The first article cited, quoted from, and included a hyperlink to a copy of HHS-OIG's March 2013 Special Fraud Alert regarding PODs, and the second article linked to the first. In connection with the second article, the newspaper interviewed Asfora. Asfora read the resulting article, forwarded it to others, and complained to MDLLC's co-owner and MDLLC's VP of Operations—who later took the same position at Sicage—that MDLLC was described as a POD.

103. Defendants understood the legal risks associated with submitting claims for surgeries in which Asfora profited from the devices he used. However, even after OIG's Special Fraud Alert in March 2013, Asfora continued to submit, and cause the Hospitals to submit, claims to federal healthcare programs resulting from kickbacks, including medically unnecessary

procedures. Asfora never identified in any of his claims to federal healthcare programs that he, the provider performing the surgeries, was profiting from the devices he surgically implanted in patients.

## SPINAL SURGERY BACKGROUND

### I. SPINAL SURGERY

104. There are four regions of the spine: the cervical, thoracic, lumbar, and sacral regions. The cervical spine consists of seven vertebrae in the neck region; the thoracic spine consists of twelve vertebrae in the chest region; the lumbar spine consists of five vertebrae in the lower back region; and the sacral spine (sacrum) consists of five vertebrae below the lumbar spine.

105. Each vertebra of the cervical, thoracic, lumbar, and sacral spine is referred to by a letter and number denoting its region and location. From top to bottom, the seven vertebrae of the cervical spine are named Cl–C7; the twelve vertebrae of the thoracic spine are named Tl–Tl2; the five vertebrae of the lumbar spine are named Ll–L5; and the five vertebrae of the sacral spine are named S1–S5.

106. A spinal fusion is a surgery that is performed to join (or "fuse") two or more vertebrae of the spine.

107. Spinal fusion surgeries can be performed in numerous ways. In a posterior fusion, the surgeon accesses the spine through an incision in the back. In a transforaminal fusion, which is an adaptation of the posterior fusion procedure, the disc space is accessed through an opening between vertebrae. In an anterior fusion, the surgeon accesses the spine through an abdominal incision.

108. While most spinal vertebrae are mobile, the sacral vertebrae of adults are joined together to form an immobile, wedge-shaped bone called the sacrum. The sacrum and the pelvis

are connected by strong ligaments, forming sacroiliac (SI) joints. In an SI joint instrumentation or SI joint fusion, the surgeon seeks to fuse the SI joint.

## II. SPINAL DEVICES

### A. Device Approval or Clearance Process

109. Spinal devices may be used in connection with a fusion surgery to help stabilize the spine and facilitate fusion. Before a vendor can market a spinal device in interstate commerce, the device must be approved or cleared by the Food and Drug Administration (FDA).

110. Premarket approval is the most stringent type of device marketing application required by the FDA. Premarket approval is based on the FDA's determination that the device marketing application contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). No device sold by MDLLC or Sicage has received premarket approval.

111. Companies can bypass the FDA's premarket approval process if they show, during a premarket notification process pursuant to Section 510(k) of the Food, Drug and Cosmetic Act, that their proposed device is "substantially equivalent" to existing, commercially-available devices. *See* 21 U.S.C. § 360e(b)(l); 21 C.F.R. § 814.l(c)(l).

112. For example, when MDLLC applied in 2009 for 510(k) clearance of a device known as the Bullet Cage, MDLLC represented to the FDA that the Bullet Cage was "substantially identical" to two commercially-available predicate devices, the Interfix Threaded Fusion Device and the Ray TFC Device. In that application, MDLLC informed the FDA that the Bullet Cage had "the same indication statements," "the same intended use," "the same technological characteristics," and was made of the same "material" (titanium alloy) as the predicate devices. MDLLC's application was supported by a certification signed by Asfora that to the best of his

knowledge all data and information in the application was "truthful and accurate." MDLLC further confirmed to the FDA in July 2009 that the Bullet Cage was "substantially equivalent to the predicate device[s] in all key device features." In August 2009, the FDA cleared MDLLC to sell the Bullet Cage for use in "spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) and instability in the lumbar spine at one or two levels from L2 to S1."

113. Likewise, when Sicage applied for 510(k) clearance of its Sicage device, it represented to FDA that the device "possesses the same technological characteristics"—including the intended use, basic design (threaded bone screw), material (titanium alloy), and sizes—as two commercially-available predicate devices, the Synthes 6.5 mm Cannulated Screw and the Silex Sacroiliac Joint Fusion System. Sicage confirmed to the FDA that "[t]he fundamental scientific technology of the SICAGE System is the same as previously cleared devices."

**B. Types of Spinal Devices**

114. During the relevant period, the types of devices described below were generally commercially available.

115. A cage is a device that may be implanted in a fusion surgery to maintain space between vertebral segments. MDLLC received as much as $4,000 per cage that Asfora surgically implanted in patients.

116. A pedicle screw is a metallic device that is implanted into the bones of the spine to facilitate the fixation of the spinal vertebrae. Pedicle screws are implanted into two or more adjacent spinal segments and are used to anchor "rods" or "plates." MDLLC received as much as $1,400 per pedicle screw that Asfora surgically implanted in patients.

117. A plate is a device that is implanted in connection with cervical surgery. A plate is anchored by screws and placed longitudinally along the front of the cervical spine. MDLLC received as much as $2,250 per plate that Asfora surgically implanted in patients.

118. A rod is a device that is placed longitudinally along the back of the lumbar and thoracic spine and is anchored by pedicle screws. MDLLC received as much as $350 per rod that Asfora surgically implanted in patients.

119. An SI screw is a device that is implanted in connection with an SI joint fusion. MDLLC received FDA clearance for an SI screw known as the Samba screw in August 2012, and Sicage received FDA clearance for an SI screw known as the Sicage device in May 2017. When surgically implanted by Asfora in patients, MDLLC received as much as $3,500 per Samba screw, and Sicage received as much as $3,250 per Sicage screw.

120. At all relevant times, Asfora selected the devices that he used in spinal surgeries at the Hospitals.

## DEFENDANTS' FALSE CLAIMS

## I. DEFENDANTS' KICKBACK SCHEMES

### A. The Bullet Cage

121. As Vondra, MDLLC's Vice President of Operations, testified, the Bullet Cage "was no longer unique" when it received FDA clearance in August 2009. At least two other titanium interbody cages were on the market, and MDLLC represented to the FDA that the Bullet Cage was "substantially equivalent" to those devices "in all key device features."

122. Vondra testified that when MDLLC began offering the Bullet Cage for sale in 2009, there was "a lot of competition," including by substantially equivalent devices. To try to convert

physicians "from what they have already been using for six, seven years and that they like," she testified, was "difficult."

123. MDLLC found it so difficult to find physicians willing to use the Bullet Cage that it offered and paid money to physicians to use the device. MDLLC offered and paid its physician-owner, Asfora, profit distributions based on his use of MDLLC devices. Asfora used his relationship with MDLLC to guarantee profits for himself through his use of MDLLC-supplied products in his own surgeries.

124. MDLLC's physician-owner, Asfora, also personally asked his neurosurgeon colleagues and acquaintances to use MDLLC devices. Asfora did so because he knew that he would profit from their use of MDLLC devices. On numerous occasions, MDLLC and Asfora offered to pay such neurosurgeons to encourage them to use MDLLC devices.

125. In or about November 2009, Asfora attended the annual meeting of the North American Spine Society (NASS) in San Francisco, California. Quentin Durward, M.D., a board-certified neurosurgeon and fellow of the American Association of Neurological Surgeons, also attended the NASS meeting. Durward performs surgery at The Center for Neurosciences, Orthopaedics & Spine in Dakota Dunes, South Dakota and Faith Regional Hospital in Norfolk, Nebraska. Asfora and Durward had known each other before the NASS meeting. Earlier in their careers, both Asfora and Durward had trained with the same neurosurgeon in Canada.

126. At the NASS meeting, Asfora spoke with Durward about the Bullet Cage.

127. Asfora offered to pay Durward $800 in cash for each Bullet Cage that Durward used. In response, Durward told Asfora that Asfora's offer did not sound legal or proper.

128. Asfora told Durward not to worry because Asfora's attorney could structure the payment as a consulting fee to make it legal. Durward refused Asfora's offer, believing it was a blatant bribe and illegal inducement.

129. In or about late 2009 and early 2010, MDLLC and Asfora offered to make monthly payments to three of Asfora's physician colleagues who were considering using the Bullet Cage. MDLLC paid those physicians thousands of dollars per month from May 2010 to April 2011. To disguise the kickbacks, MDLLC described the payments as "consulting fees."

130. Before the fee payments, those three physicians had infrequently or sporadically used MDLLC's Bullet Cage device. During the period in which they received the fee payments, the three physicians regularly used the Bullet Cage in their surgeries. After the fee payments ceased, the three physicians ceased regularly using the Bullet Cage.

131. During the period of the fee payments, MDLLC paid each of the three physicians a fixed monthly sum of money, which did not vary regardless of the amount of time, if any, that the physician spent performing consulting work for MDLLC that month.

132. MDLLC paid different amounts of consulting fees to the three physicians. Of the three physicians, MDLLC paid the most per month to the physician who used the most Bullet Cages, and the least per month to the physician who used the fewest Bullet Cages. Specifically, MDLLC paid $10,000 per month to Wellman, the physician who used the most Bullet Cages other than Asfora; $5,000 per month to the physician who used the next highest number of Bullet Cages; and $3,000 per month to the physician who used the fewest Bullet Cages.

133. A number of Asfora's colleagues raised concerns about MDLLC's payments to the physicians who used the MDLLC devices in surgeries at SMC. For example, a Sanford Clinic surgeon warned SMC that Asfora "owns the company that makes the [Bullet] cages," "has an

income from the use of the cages," and since the FDA clearance has been using the cages "almost exclusively" and "doing a large number of multiple level spinal fusions," such that he was "an 'outlier' when compared to other spine surgeons."

134. Sanford Health's Chief Compliance Officer (CCO) began investigating such concerns in late 2010, aware of the risk that MDLLC's payments were "kickbacks that would be in violation of [the] Anti-Kickback [Statute]." In particular, she was concerned about whether the physicians were "getting paid for using [MDLLC devices] in a back door way" as purported consulting fees. However, despite her repeated requests to MDLLC and Asfora, they refused to provide her with copies of the consulting agreements, telling her the matter was "[n]one of [her] business."

135. In September 2011, MDLLC and Asfora each were served with subpoenas by HHS-OIG in connection with an investigation of possible violations of federal healthcare fraud statutes, including the AKS. In December 2013, MDLLC and Asfora settled allegations that they had violated the FCA and AKS, among other laws, as a result of MDLLC's consulting fee payments from May 2010 to April 2011, where such payments were intended to induce the recipients to promote and/or use Bullet Cages. MDLLC and Asfora signed the settlement agreement on December 19, 2013.

136. Despite being under investigation for paying consulting fee kickbacks, MDLLC and Asfora were engaged in other kickback schemes at the same time, offering physicians another way to profit from their use of MDLLC products. In February 2012, MDLLC offered to extend the type of kickback it was paying to Asfora—profit distributions based on his use of MDLLC products—to neurosurgeons Wellman and Troy Gust, M.D. That month, MDLLC's physician-owner, Asfora, offered Wellman and Gust an opportunity to invest in or become an owner of

MDLLC in order to receive the profits that they would generate from their use of products sold by MDLLC, such as the Bullet Cage.

137. Wellman and Gust refused MDLLC's offer. On February 24, 2012, Wellman and Gust's counsel sent a letter to Asfora and MDLLC's counsel, confirming in writing that "neither Drs. Wellman nor Gust are interested in forming any type of health care entity or joint venture with Dr. Asfora." Wellman and Gust's counsel stated, "[w]e wish to be clear that this is not a negotiation, simply a clarification of intent . . . ."

138. Even though Wellman had refused MDLLC's profit distributions kickback offer, MDLLC and Asfora offered Wellman a new type of kickback about four months later. On July 2, 2012, MDLLC's physician-owner, Asfora, offered to pay Wellman $1,000 for each Bullet Cage that Wellman used in surgery.

139. To justify the offer, Asfora told Wellman that they got into trouble doing it "the right way"—by paying consulting fees—so this time Wellman would be paid under the table, without a trail, and no one would know. Wellman rejected Asfora's offer and told him it was illegal.

140. Physicians without a financial reason to use the Bullet Cage rarely did so. Over 90% of MDLLC's sales of the Bullet Cage from 2012 to 2018 were to the Hospitals for Asfora's use. No physician other than Asfora, who receives profit distributions from MDLLC, and the three physicians who received consulting fees from MDLLC, has regularly used the Bullet Cage. No physician outside of Sioux Falls, South Dakota has regularly used the Bullet Cage.

141. Despite numerous warnings, MDLLC continued paying to Asfora, and Asfora continued soliciting and receiving from MDLLC, profit distributions based on Asfora's use of the Bullet Cage and other products distributed by MDLLC. *See* Sections I.B.-E., *infra*.

142. By paying profit distributions to Asfora, MDLLC secured Asfora's and the Hospitals' business and generated millions of dollars in revenue. From June 1, 2011 to December 31, 2018, MDLLC's primary source of revenue was its sale of medical products, nearly all of which were sold to the Hospitals for Asfora's use. During that period, Asfora generated hundreds of thousands of dollars per year in revenue for MDLLC based on his use of MDLLC products, and MDLLC distributed the resulting profits, directly or indirectly, and in a variety of types of payments, to Asfora and his wife. For example:

a. In 2012, MDLLC paid over $14,500 to a corporate entity owned and controlled by Asfora, and agreed to pay over $190,000 directly to Asfora and over $190,000 to Asfora's wife.

b. In 2013, MDLLC paid over $75,000 to a corporate entity owned and controlled by Asfora and over $20,000 directly to Asfora.

c. In 2014, MDLLC paid over $1,600,000 directly to Asfora, over $750,000 to Asfora's wife, and over $60,000 to two corporate entities owned and controlled by Asfora.

d. In 2015, MDLLC paid over $215,000 directly to Asfora, over $170,000 to Asfora's wife, and over $40,000 to two corporate entities owned and controlled by Asfora.

e. In 2016, MDLLC paid over $265,000 directly to Asfora, at least $100,000 to Asfora's wife, and over $40,000 to a corporate entity owned and controlled by Asfora.

f. In 2017, MDLLC paid at least $225,000 directly to Asfora, at least $225,000 to Asfora's wife, and over $40,000 to a corporate entity owned and controlled by Asfora.

g. In 2018, MDLLC paid at least $50,000 directly to Asfora, at least $50,000 to Asfora's wife, and over $44,000 to a corporate entity owned and controlled by Asfora.

143. Such payments included rent paid from MDLLC to a corporate entity owned and controlled by Asfora, paid monthly or as MDLLC generated enough cash to make the payment.

144. MDLLC made the above-referenced payments to Asfora, his wife, and corporate entities owned and controlled by Asfora using checks drawn from MDLLC's First National Bank account (ending in 1818). Asfora and his wife deposited those checks in their bank accounts and the accounts of corporate entities owned and controlled by Asfora.

**B. Amendia Products**

145. While under investigation in 2012 for violating the AKS by paying consulting fee kickbacks, MDLLC and Asfora entered into another arrangement to compensate Asfora for his use of medical devices.

146. In or about February and March 2012, MDLLC and Amendia discussed allowing MDLLC to resell Amendia products for use in Asfora's surgeries. In this arrangement, MDLLC would act as a middleman taking a cut of the profits on each sale of Amendia's spinal products when Asfora used the products in his surgeries. MDLLC solicited from Amendia a valuable license to resell the products, and agreed to purchase (at a fraction of the resale price) the products as needed for Asfora's use, to resell the products at a steep markup to hospitals for Asfora's use, and to share the profits with Asfora.

147. Under this arrangement, MDLLC would act as a physician-owned distributor of Amendia's products. Amendia, however, had a written corporate compliance policy titled "Arrangements with Physician-Owned Distributors," which its counsel had drafted one year earlier. In or about March 2012, Amendia sent its compliance policy and a letter from its counsel to MDLLC and Asfora.

148. In the letter, Amendia's counsel advised that "PODs are in the crosshairs of the Department of Health and Human Services, both from an anti-kickback and a Stark law

perspective. There is not an available safe harbor or exception to those laws to protect POD arrangements, leaving such arrangements open to scrutiny."

149. Under Amendia's policy, the company was required to conduct due diligence before entering into any type of arrangement with a POD. The policy specified twelve compliance items that must be satisfied either by documentation from the POD or an affidavit from an officer of the POD. Among other things, Amendia's policy required that "[t]he POD is currently servicing multiple Providers or anticipates broadening its customer base to include multiple Providers, including hospitals or ambulatory surgery centers at which the physician owners of the POD do not have medical staff privileges." The policy also required that "[t]he POD has performed a regulatory analysis for compliance with the federal Medicare and Medicaid anti-kickback statute and the federal physician self-referral law as well as any applicable state fraud and abuse laws and has determined that the POD is operating in a manner that would not violate such laws."

150. After receiving Amendia's policy, MDLLC told Amendia on March 30, 2012 that MDLLC "should have the agreement completed on Monday." However, nearly three weeks later, Amendia was still waiting for MDLLC to provide a written agreement "if [MDLLC's counsel] has blessed it."

151. In May and early-June 2012, before any written agreement with Amendia was formalized or signed, MDLLC distributed for a profit the following Amendia products for Asfora's use: (1) Amendia's Savannah-T Pedicle Screw System, which included pedicle screws, rods, Kirschner (or "K")-wires, and set screws; and (2) Amendia's Diamond System, which included cervical plates, variable screws, and cervical drill bits.

152. Ultimately, on June 13, 2012, MDLLC and Asfora's counsel wrote to Amendia regarding MDLLC and "the distribution of Amendia products," stating that "things have worked

out" such that the existing distributor of Amendia products in Sioux Falls, South Dakota—rather than MDLLC—will be "doing all the distribution" of Amendia products.

153. During May and early-June 2012, when MDLLC could profit from Asfora's use of the devices pursuant to its arrangement with Amendia, Asfora often used Amendia's products in his surgeries. However, Asfora rarely, if ever, used Amendia's Savannah-T and Diamond products before MDLLC's arrangement with Amendia, and rarely, if ever, used such products after MDLLC ended its arrangement with Amendia.

**C. Life Spine Products**

154. While under investigation for violating the AKS by paying consulting fee kickbacks, MDLLC's physician-owner, Asfora, told a sales representative at Merging Medical Solutions Inc., Jesse Talcott, that MDLLC should own the products that Asfora uses for spinal surgery, so that MDLLC and Asfora could make money when Asfora used those products.

155. MDLLC directed Talcott to find a company that would allow MDLLC to resell its products for Asfora's use. Talcott did so. A number of companies would not participate in the proposed scheme to allow a physician-owned company to profit from the resale of devices for the physician-owner's use. However, medical device company Life Spine Inc. (Life Spine) agreed to participate, and Talcott told MDLLC and Asfora that Life Spine was a potential partner. MDLLC sought and received from Life Spine the ability to resell Life Spine products for a profit. MDLLC agreed to markup and resell Life Spine's products, and Asfora agreed to use Life Spine's products in exchange for profit distributions from MDLLC.

156. In contrast to Amendia, Life Spine neither had a written compliance policy concerning PODs, nor asked MDLLC for compliance documentation or an affidavit. Unlike the Amendia arrangement, MDLLC distributed Life Spine's products for a lengthy period of time.

From May 2012 to January 2014, MDLLC purchased from Life Spine its NEO-SL Anterior Cervical Plate System (NEO-SL) products, including cervical plates, variable screws, and cervical drill bits. From July 2012 to May 2014, MDLLC purchased from Life Spine its Avatar Pedicle System (Avatar) products, including pedicle screws, rods, Kirschner (or "K")-wires, and set screws.

157. MDLLC and Asfora sought to profit from Asfora's use of Life Spine products at SMC in May and June 2012. MDLLC invoiced those Life Spine products to Sanford Health, which paid numerous invoices, totaling thousands of dollars.

158. However, on or about June 13, 2012, Sanford told MDLLC and Asfora that MDLLC was not allowed to sell Life Spine products for Asfora's use at SMC. As MDLLC's VP of Operations testified, she understood that Sanford would not purchase another company's products that MDLLC was reselling "[b]ecause they didn't want to do any business with anything that was a physician-owned distributor, anything that was a POD."

159. On June 14, 2012, MDLLC prepared and subsequently sent a letter to Sanford Health, asking it to "void" its prior check that had paid four invoices for Amendia and Life Spine products. MDLLC confirmed to Sanford Health that "the only items that are being billed through [MDLLC]" are the Bullet Cage and another MDLLC product, the Dakota Knife.

160. Despite the warnings from Amendia and Sanford, MDLLC continued reselling Life Spine products. Specifically, from July 2012 to May 2014, MDLLC resold Life Spine's NEO-SL and Avatar products to SFSH for Asfora's use in surgeries.

161. The below chart depicts the prices MDLLC generally paid to Life Spine to purchase NEO-SL products, the prices at which MDLLC resold those products to SFSH, and the gross profits MDLLC generated from each sale:

| NEO-SL Products | MDLLC's Purchase Price (Per Unit) | MDLLC's Re-Sale Price (Per Unit) | MDLLC's Gross Profit (Per Unit) |
|---|---|---|---|
| **Cervical Plate** | $500.00 | $1,900.00 | $1,400.00 |
| **Variable Screw** | $125.00 | $250.00 | $125.00 |
| **Cervical Drill Bit** | $200.00 | $250.00 | $50.00 |

162. Although on occasion MDLLC paid Life Spine $700 per cervical plate, MDLLC still was able to resell each such plate to SFSH for $1,900 per plate, generating a gross profit of $1,200 per plate.

163. The below chart depicts the prices MDLLC paid to Life Spine to purchase Avatar products, the prices at which MDLLC resold those products to SFSH, and the gross profits MDLLC generated from each sale:

| Avatar Products | MDLLC's Purchase Price (Per Unit) | MDLLC's Re-Sale Price (Per Unit) | MDLLC's Gross Profit (Per Unit) |
|---|---|---|---|
| **Pedicle Screw** | $600.00 | $1,400.00 | $800.00 |
| **Rod** | $175.00 | $350.00 | $175.00 |
| **K-Wire** | $75.00 | $206.50 | $131.50 |
| **Set Screw** | $80.00 | $160.00 | $80.00 |

164. Neither MDLLC nor Asfora invented, designed, manufactured, advertised, marketed, sterilized, or packaged any of the Life Spine NEO-SL or Avatar products. Instead, MDLLC simply received the Life Spine products at its office and delivered them to SFSH for use in Asfora's surgeries.

165. In May and June 2012, MDLLC sold the Life Spine products to only the Hospitals, and only for Asfora's use. After June 2012, MDLLC sold the Life Spine products to only SFSH, and only for Asfora's use.

166. MDLLC ordered the Life Spine products as needed for Asfora's surgeries, rather than purchase an inventory, and thus had little if any storage costs and no risk.

167. By purchasing small quantities as needed, and immediately reselling them to SFSH for use in Asfora's surgeries, MDLLC generated significant revenue and extraordinary profits.

168. MDLLC received over $355,000 in revenue based on the resale of Life Spine's Avatar products for Asfora's use. With those products, MDLLC could—and did—buy and resell pedicle screws for an immediate 133% return; K-wires for a 175% return; and rods and set screws for a 100% return. In total, MDLLC's gross profit on its resale of Avatar products for Asfora's use exceeded $200,000—an overall return of over 130% for the Avatar products it resold for Asfora's use.

169. MDLLC received over $125,000 in revenue based on the resale of Life Spine's NEO-SL products for Asfora's use. With those products, MDLLC could—and did—buy and resell cervical plates for an immediate 280% return; variable screws for a 100% return; and drill bits for a 25% return. In total, MDLLC's gross profit on its resale of NEO-SL products for Asfora's use exceeded $70,000—an overall return of over 140% for the NEO-SL products it resold for Asfora's use.

170. Asfora regularly used Life Spine's Avatar and NEO-SL products during the time period in which MDLLC was able to profit from the resale of those products for Asfora's use.

171. For example, on or about [redacted], 2013, Asfora implanted one Life Spine cervical plate and eight Life Spine variable screws in patient [redacted] (DOB [redacted]/1961) at SFSH, using one Life Spine drill bit. SFSH billed Medicare for the inpatient services and received a Medicare Part A payment of over $11,000. Asfora billed Medicare for his professional services and received a Medicare Part B payment of over $2,650. SFSH paid MDLLC $4,150 for the Life Spine devices used in the surgery.

172. As another example, on or about [redacted] 2013, Asfora implanted one Bullet Cage, two Life Spine pedicle screws, and two Life Spine rods in patient [redacted] (DOB [redacted]/1933) at SFSH, using two Life Spine K-wires. SFSH billed Medicare for the inpatient

services and received a Medicare Part A payment of over $20,850. Asfora billed Medicare for his professional services and received a Medicare Part B payment of over $2,650. For the devices used in the surgery, SFSH paid MDLLC $4,000 for the Bullet Cage and over $3,900 for the Life Spine devices, for a total of over $7,900.

173. As still another example, on or about [redacted], 2013, Asfora implanted eight Bullet Cages, five Life Spine pedicle screws, and one Life Spine rod in patient [redacted] (DOB [redacted] 1953) at SFSH, using five Life Spine K-wires. SFSH billed TRICARE for the inpatient services and received a TRICARE payment of over $33,800. Asfora billed TRICARE for his professional services and received a TRICARE payment of over $6,200. For the devices used in the surgery, SFSH paid MDLLC $32,000 for the Bullet Cages and over $7,300 for the Life Spine devices, for a total of over $39,300.

174. Asfora rarely, if ever, used Life Spine's Avatar and NEO-SL products before MDLLC's arrangement with Life Spine, and rarely, if ever, used such products after MDLLC ended its arrangement with Life Spine.

**D. Aegis Spine Products**

175. In January 2014, one month after settling allegations of paying consulting fee kickbacks, MDLLC and its physician-owner, Asfora, met with the CEO of Aegis Spine Inc. (Aegis) to discuss an arrangement by which MDLLC and Asfora could profit when Asfora implanted Aegis products in patients.

176. By January 2014, Aegis already had a non-physician distributor, Peter Sanchez (Sanchez), who transacted business in Sioux Falls, South Dakota and could distribute Aegis products for Asfora to use at the Hospitals. By March 12, 2014, Aegis had a second non-physician distributor, Talcott, who transacted business in Sioux Falls, South Dakota and could distribute

Aegis products for Asfora to use at the Hospitals. At that time, MDLLC was not a distributor of Aegis products. Although Asfora could have used Aegis products distributed by Sanchez or Talcott, neither MDLLC nor Asfora would have profited from such use.

177. Despite knowing, by March 2014, that Aegis already had two distributors in South Dakota, MDLLC and Asfora sought from Aegis an alternative arrangement by which they would make money from Asfora's use of Aegis products. On or about March 19, 2014, MDLLC began purchasing products from Aegis to resell to hospitals for Asfora's use in surgeries.

178. Effective April 10, 2014, MDLLC entered into a written agreement with Aegis "to purchase Products from [Aegis] for resale to hospitals or other licensed healthcare facilities ('Facilities') for use in surgical procedures performed at such Facilities."

179. Pursuant to the agreement, Aegis granted MDLLC "the right to distribute" Aegis products, including the pedicle screw and cervical plate systems, "solely within the Territory," which was defined as SMC, SFSH, and one other hospital in Sioux Falls, South Dakota. Specifically, Aegis granted MDLLC "a nontransferable, royalty free, non-exclusive license under any and all Product Intellectual Property Rights to import, use, repair, sell and offer for sale the Products . . . ."

180. The agreement allowed MDLLC to order Aegis products as needed; pay Aegis only for the products "consumed" (i.e., used in surgery); pay Aegis within 60 days of the end of the month in which products were consumed; and return and receive a refund for unconsumed products. Thus, not only would MDLLC have a guaranteed customer in Asfora, its co-owner, but MDLLC would bear little if any financial risk under the Aegis arrangement.

181. MDLLC and Asfora knew how much they would profit from the sale of Aegis products, due to communications with Talcott, and receipt of capitated price lists from Sanford Health and SFSH, which detailed how much those hospitals would pay for spinal devices.

182. Despite MDLLC and its owners bearing little risk, the Aegis agreement allowed MDLLC to receive hundreds of dollars in profit per Aegis product that Asfora used, totaling thousands of dollars of profit per surgery that Asfora performed.

183. On April 9, 2014, one day before the effective date of the Aegis-MDLLC agreement, MDLLC and Asfora received a letter from their counsel. Their counsel stated that he had reviewed the Aegis agreement, which he found to be "a very favorable agreement" and in fact "may actually be too favorable."

184. Asfora and MDLLC's counsel warned that "[t]he biggest issue I see pertains to compliance." "Under the anti-kickback statute," counsel explained, "there is liability for any agreement if one purpose of it is to induce referrals. In this case, the argument would be that this distributorship is being entered into in order to ensure that Dr. Asfora continues to use the Aegis Spine Inc. products." Counsel noted that Aegis "ha[s] a representative right now in our area that does sales for a living," and in contrast, MDLLC "has no hired representatives."

185. Asfora and MDLLC's counsel noted that he had "discussed with Dr. Asfora" possible alternatives, such as "tak[ing] no profit on devices utilized by him [Asfora] personally," but that approach "would largely defeat the benefit of the distribution agreement."

186. Counsel advised MDLLC and Asfora that, under the proposed arrangement, Aegis would be "covering our carrying costs," MDLLC would be "taking almost no risk," MDLLC could "guarantee that the product will be utilized," and "with the 60 day float" MDLLC would "be able to effectively order on a case-by-case basis, and will profit from the same."

187. Counsel warned Asfora and MDLLC: "In addition to making us a traditional POD which is subject to extraordinary scrutiny by the OIG, this [arrangement with Aegis] will also be one where we will likely receive a high return on a very low risk venture."

188. Counsel emphasized to MDLLC and Asfora, "I hate to be the bearer of bad news but this would certainly expose us to a potential *qui tam* claim or an independent investigation by the government." While defenses could be raised, counsel advised, "it would be a tough case."

189. In conclusion, counsel advised MDLLC and Asfora to make a decision "with both eyes wide open" to the consequences.

190. That same day, April 9, 2014, after receiving counsel's letter, Asfora stated, "I do not entirely agree" with counsel's legal advice. Asfora stated, "I have decided to sign the contract," and noted that he planned to "sell to all hospitals" and would "use the devices."

191. Rejecting their attorney's advice, MDLLC and Asfora signed the distribution agreement with Aegis on April 18, 2014. MDLLC and Asfora refused to take any steps to address the concerns raised by their counsel. Instead, they moved ahead with their plan to profit from Asfora's use of Aegis products at the Hospitals.

192. Asfora's wife, a co-owner of MDLLC, who discussed the proposed Aegis deal with Asfora and MDLLC's counsel, testified that there were "compliance concerns" and "the whole conversation going forward on this was it's not a good idea and there could be serious issues down the road." She testified that the Aegis arrangement concerned her and "just didn't feel right."

**1. Sales of Aegis Products to SFSH**

193. From March 2014 to February 2015, despite the concerns expressed to MDLLC, MDLLC purchased Aegis' pedicle screw system and cervical plate system products and resold them at a significant profit to SFSH for Asfora's use. The below chart depicts the prices MDLLC

paid to Aegis to purchase its pedicle screw system and cervical plate system products, the prices at which MDLLC resold those products to SFSH, and the gross profits MDLLC generated from each sale from March 2014 to February 2015:

| Aegis Products | MDLLC's Purchase Price (Per Unit) | MDLLC's Resale Price to SFSH (Per Unit) | MDLLC's Gross Profit (Per Unit) |
|---|---|---|---|
| **Pedicle Screw** | $300.00 | $1,400.00 | $1,100.00 |
| **Straight Rod** | $100.00 | $350.00 | $250.00 |
| **Curved Rod** | $80.00 | $350.00 | $270.00 |
| **Set Screw** | $30.00 | $80.00 | $50.00 |
| **Cervical Plate** | $350.00 | $1,900.00 | $1,550.00 |
| **Cervical Plate Screw** | $60.00 | $250.00 | $190.00 |

194. By distributing Aegis products to SFSH for Asfora's surgeries, MDLLC could—and did—buy and resell cervical plates for an immediate 443% return; pedicle screws for a 367% return; curved rods for a 338% return; cervical plate screws for a 317% return; straight rods for a 250% return; and set screws for a 167% return.

195. For example, on or about [redacted], 2014, Asfora implanted two Bullet Cages, one Aegis pedicle screw, one Aegis set screw, one Aegis curved rod, and three Samba screws in patient [redacted] (DOB [redacted]/1930) at SFSH, using three sharp Steinmann pins, one long blunt Steinmann pin, one short blunt Steinmann pin, three drill bits, and one packing tube. SFSH billed Medicare for the inpatient services and received a Medicare Part A payment of over $32,350. Asfora billed Medicare for his professional services and received a Medicare Part B payment of over $3,450. For the devices used in the surgery, SFSH paid MDLLC $8,000 for the Bullet Cages, over $1,800 for the Aegis devices, and over $14,200 for the Samba products, for a total of over $24,000.

196. As another example, on or about [redacted], 2014, Asfora implanted six Bullet Cages, four Aegis pedicle screws, four Aegis set screws, and one Aegis curved rod in patient [redacted] (DOB [redacted]/1949) at SFSH. SFSH billed Medicare for the inpatient services and

received a Medicare Part A payment of over $21,700. Asfora billed Medicare for his professional services and received a Medicare Part B payment of over $4,250. For the devices used in the surgery, SFSH paid MDLLC $24,000 for the Bullet Cages and over $6,000 for the Aegis devices, for a total of over $30,000.

197. In September 2014, SFSH notified Asfora and MDLLC that it would be terminating MDLLC's purchase order agreement. SFSH raised concerns that MDLLC was operating as a POD by selling devices to SFSH for use by MDLLC's physician-owner, Asfora.

198. Rather than cease to resell products at a profit for Asfora's use in surgeries, MDLLC then used a middleman to resell Aegis products to SFSH at a profit for use in Asfora's surgeries. From March 2015 to September 2015, MDLLC purchased pedicle screw system products from Aegis and resold them to Innovative Medical Solutions, LLC (IMS), a company owned by Talcott, to be resold to SFSH for Asfora's use in surgeries. During that time period, the below chart depicts the prices MDLLC paid to Aegis to purchase those products, the prices at which MDLLC resold those products to IMS, and the gross profits MDLLC generated from each sale:

| Aegis Products | MDLLC's Purchase Price (Per Unit) | MDLLC's Resale Price to IMS (Per Unit) | MDLLC's Gross Profit (Per Unit) |
|---|---|---|---|
| **Pedicle Screw** | $300.00 | $750.00 | $450.00 |
| **Straight Rod** | $100.00 | $150.00 | $50.00 |
| **Curved Rod** | $80.00 | $150.00 | $70.00 |
| **Set Screw** | $30.00 | $50.00 | $20.00 |

199. By distributing Aegis products to IMS for Asfora's surgeries at SFSH, MDLLC could—and did—buy and resell pedicle screws for an immediate 150% return; curved rods for an 88% return; set screws for a 67% return; and straight rods for a 50% return.

200. For example, on or about [redacted], 2015, Asfora implanted ten Bullet Cages, six Aegis pedicle screws, six Aegis set screws, and one Aegis straight rod in patient [redacted]

(DOB [redacted]/1948) at SFSH. SFSH billed Medicare for the inpatient services and received a Medicare Part A payment of over $42,000. Asfora billed Medicare for his professional services and received a Medicare Part B payment of over $5,875. For the devices used in the surgery, MDLLC received $40,000 from SFSH for the Bullet Cages, and over $4,900 for the Aegis devices, for a total of over $44,900.

**2. Sales of Aegis Products to Sanford**

201. At Sanford, MDLLC and Asfora implemented a similar middleman scheme. They did so because Sanford had previously told them that it would not purchase another company's products that MDLLC was reselling. Rather than comply with this policy, MDLLC and Asfora covertly circumvented it.

202. From March 2014 to October 2015, MDLLC purchased pedicle screw system products from Aegis and resold them to IMS to be sold to SMC for use in Asfora's surgeries.

203. From March 2014 to mid-March 2015, the below chart depicts the prices MDLLC paid to Aegis to purchase those products, the prices at which MDLLC resold those products to IMS, and the gross profits MDLLC generated from each sale:

| Aegis Products | MDLLC's Purchase Price (Per Unit) | MDLLC's Resale Price to IMS (Per Unit) | MDLLC's Gross Profit (Per Unit) |
|---|---|---|---|
| **Pedicle Screw** | $300.00 | $500.00 | $200.00 |
| **Straight Rod** | $100.00 | $150.00 | $50.00 |
| **Curved Rod** | $80.00 | $125.00 | $45.00 |
| **Set Screw** | $30.00 | $40.00 | $10.00 |

204. By distributing Aegis products to IMS for Asfora's surgeries at SMC, MDLLC could—and did—buy and resell pedicle screws for an immediate 67% return; curved rods for a 56% return; straight rods for a 50% return; and set screws for a 33% return.

205. For example, on or about [redacted], 2014, Asfora implanted six Bullet Cages, eight Aegis pedicle screws, eight Aegis set screws, and two Aegis straight rods in patient [redacted]

(DOB [redacted]/1963) at SMC. SMC billed Medicare for the inpatient services and received a Medicare Part A payment of over $25,900. Asfora billed Medicare for his professional services and received a Medicare Part B payment of over $4,250. For the devices used in the surgery, MDLLC received $13,830 from SMC for the Bullet Cages, and $4,620 for the Aegis devices, for a total of $18,450.

206. As another example, on or about [redacted] 2014, Asfora implanted five Bullet Cages, six Aegis pedicle screws, six Aegis set screws, and one Aegis straight rod in patient [redacted] (DOB [redacted]/1947) at SMC. SMC billed Medicare for the inpatient services and received a Medicare Part A payment of over $31,650. Asfora billed Medicare for his professional services and received a Medicare Part B payment of over $5,800. For the devices used in the surgery, MDLLC received $11,525 from SMC for the Bullet Cages, and $3,390 for the Aegis devices, for a total of over $14,900.

207. In mid-March 2015, MDLLC raised the prices that IMS paid to purchase the Aegis pedicle screw system products to resell to SMC for Asfora's use. From mid-March 2015 to October 2015, the prices MDLLC paid to Aegis to purchase those products, the prices at which MDLLC resold those products to IMS, and the gross profits MDLLC generated from each sale are listed in paragraph 198, *supra*. The returns that MDLLC generated on such sales are listed in paragraph 199, *supra*.

208. For example, on or about [redacted] 2015, Asfora implanted one Bullet Cage, two Aegis pedicle screws, two Aegis set screws, and one Aegis curved rod in patient [redacted] (DOB [redacted]/1940) at SMC. SMC billed Medicare for the inpatient services and received a Medicare Part A payment of over $24,000. For the devices used in the surgery, MDLLC received $2,305 from SMC for the Bullet Cage, and $1,750 for the Aegis devices, for a total of over $4,500.

209. As another example, on or about [redacted] 2015, Asfora implanted one Bullet Cage, five Aegis pedicle screws, five Aegis set screws, and one Aegis straight rod in patient [redacted] (DOB [redacted]/1939) at SMC. SMC billed Medicare for the inpatient services and received a Medicare Part A payment of over $23,800. Asfora billed Medicare for his professional services and received a Medicare Part B payment of over $5,300. For the devices used in the surgery, MDLLC received $2,305 from SMC for the Bullet Cage, and $4,150 for the Aegis devices, for a total of over $6,450.

210. MDLLC received over $650,000 in revenue and a gross profit of over $400,000 from its distribution of Aegis products for Asfora's use—a total return of over 155%.

211. Neither MDLLC nor Asfora invented, designed, manufactured, advertised, marketed, sterilized, or packaged any of the Aegis products. Instead, MDLLC simply received the Aegis products at its office and delivered them, if necessary, to the Hospitals or IMS for use in Asfora's surgeries.

### 3. Sanford's Investigation of the Aegis Kickback Scheme

212. By August 2015, numerous physicians had warned Sanford that Asfora was receiving kickbacks to use Aegis devices. In response to the allegations, Sanford opened a compliance investigation.

213. At the end of August 2015, Sanford's CCO interviewed Asfora. Before the interview, Asfora was informed that Sanford was conducting a compliance investigation involving his conduct. Sanford asked Asfora to provide truthful answers to Sanford's questions, and Asfora knew that Sanford would rely on his statements during the compliance investigation.

214. During his interview, Asfora represented to Sanford that MDLLC had sold the Aegis products to Talcott's company, IMS, at "cost + small adm[inistrative] fee." This representation by Asfora was false.

215. Asfora did not correct his representation to Sanford. Indeed, Asfora withheld from Sanford additional information that would have shown his representation to be false. During the relevant period, Asfora did not disclose to Sanford that MDLLC was buying Aegis pedicle screws for $300 per screw and marking them up to $750 per screw to sell to IMS. During his interview, Asfora did not disclose to Sanford that the so-called "small adm[inistrative] fee" on MDLLC's resale of Aegis pedicle screws was $450 per screw. Nor did Asfora disclose to Sanford that such fee was in fact 150% of the purchase price of such Aegis pedicle screws. Nor did Asfora disclose to Sanford the marked-up resale prices listed in paragraph 198 for other Aegis products. MDLLC also failed to disclose to Sanford any of the information in this paragraph.

216. Asfora and MDLLC also withheld from the Medicare, Medicaid, and TRICARE programs any information that MDLLC was profiting from Asfora's use of Aegis products in his surgeries at SMC, including the information in the previous paragraph.

217. After August 2015, relying on Asfora's false representation that MDLLC was receiving only a small administrative fee when Asfora used Aegis products, SMC continued to submit claims to federal healthcare programs for surgeries in which Asfora had used Aegis products in which he and MDLLC had a financial interest.

218. For example, on November 30, 2015, SMC submitted its annual cost report on Form CMS-2552 to CMS for the time period of July 1, 2014 to June 30, 2015. On November 29, 2016, SMC submitted its annual cost report on Form CMS-2552 to CMS for the time period of July 1, 2015 to June 30, 2016.

219. For each time period from 2011 to 2018, SMC's Form CMS-2552 annual reports included SMC's claims to Medicare for Asfora's spinal surgeries. In each report, SMC acknowledged that if any services identified in the report "were provided or procured through the

payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil, and administrative action, fines, and/or imprisonment may result." Relying on Asfora's false representation, SMC falsely certified that the services identified in the report "were provided in compliance with [the] laws and regulations" regarding the provision of healthcare services.

**E. Samba Products**

220. As with the Bullet Cage, MDLLC and Asfora sought to profit from Asfora's use of the Samba screw system, which included the Samba screw, Steinmann pins, drill bits, and packing tube (collectively, Samba products). From December 2012 to November 2013, MDLLC paid to Asfora, and Asfora solicited and received from MDLLC, profit distributions based on Asfora's use of Samba products at SMC.

221. The below chart depicts the revenue and gross profits that MDLLC generated by selling Samba products to SMC from December 2012 to November 2013:

| Samba Products | MDLLC's Cost of Goods Sold (Per Unit) | MDLLC's Sale Price (Per Unit) | MDLLC's Gross Profit (Per Unit) |
|---|---|---|---|
| **Samba Screw** | $108.95 or less | $3,250.00 | $3,141.05 or more |
| **Variable Drill Bit** | $189.50 | $658.00 | $468.50 |
| **Packing Tube** | $46.50 | $325.50 | $279.00 |
| **Long Blunt Steinmann Pin** | $7.00 | $70.00 | $63.00 |
| **Short Blunt Steinmann Pin** | $5.00 | $49.00 | $44.00 |
| **Sharp Steinmann Pin** | $4.50 | $210.00 | $205.50 |

222. By selling Samba products for Asfora's surgeries at SMC, MDLLC received returns of over 2,880% for Samba screws; over 4,560% for sharp Steinmann pins; 900% for long blunt Steinmann pins; 880% for short blunt Steinmann pins; 600% for packing tubes; and over 240% for variable drill bits.

223. The below chart depicts the revenue and gross profits that MDLLC generated by selling Samba products to SFSH from December 2012 to September 2016:

| Samba Products | MDLLC's Cost of Goods Sold (Per Unit) | MDLLC's Sale Price (Per Unit) | MDLLC's Gross Profit (Per Unit) |
|---|---|---|---|
| **Samba Screw** | $108.95 or less | $3,500.00 | $3,391.05 or more |
| **Variable Drill Bit** | $189.50 | $940.00 | $750.50 |
| **Packing Tube** | $46.50 | $465.00 | $418.50 |
| **Long Blunt Steinmann Pin** | $7.00 | $100.00 | $93.00 |
| **Short Blunt Steinmann Pin** | $5.00 | $70.00 | $65.00 |
| **Sharp Steinmann Pin** | $4.50 | $100.00 | $95.50 |

224. By selling Samba products to SFSH for Asfora's surgeries there, MDLLC received returns of over 3,100% for Samba screws; over 2,100% for sharp Steinmann pins; over 1,300% for long blunt Steinmann pins; 1,300% for short blunt Steinmann pins; 900% for packing tubes; and over 390% for variable drill bits.

225. For example, on or about [redacted] 2013, Asfora implanted three Samba screws in patient [redacted] (DOB [redacted]/1946) at SMC, using three sharp Steinmann pins, one long blunt Steinmann pin, one short blunt Steinmann pin, and three drill bits. SMC billed Medicare for the inpatient services and received a Medicare Part A payment of over $24,000. Asfora billed Medicare for his professional services and received a Medicare Part B payment of over $795. SMC paid MDLLC over $12,470 for the Samba products used in the surgery.

226. On or about [redacted] 2013, Asfora implanted three additional Samba screws in the same patient at SMC, using three sharp Steinmann pins, one long blunt Steinmann pin, one short blunt Steinmann pin, three drill bits, and one packing tube. SMC billed Medicare for the inpatient services and received a Medicare Part A payment of over $25,700. Asfora billed Medicare for his professional services and received a Medicare Part B payment of over $795. SMC paid MDLLC over $12,790 for the Samba products used in the surgery.

227. As another example, on or about [redacted] 2013, Asfora implanted three Samba screws in patient [redacted] (DOB [redacted]/1957) at SFSH, using three sharp Steinmann pins, one long blunt Steinmann pin, one short blunt Steinmann pin, three drill bits, and

one packing tube. SFSH billed Medicare for the inpatient services and received a Medicare Part A payment of over $21,250. Asfora billed Medicare for his professional services and received a Medicare Part B payment of over $795. SFSH paid MDLLC over $14,250 for the Samba products used in the surgery.

228. On or about [redacted], 2013, Asfora implanted two additional Samba screws in the same patient at SFSH, using three sharp Steinmann pins, one long blunt Steinmann pin, one short blunt Steinmann pin, three drill bits, and one packing tube. SFSH billed Medicare for the inpatient services and received a Medicare Part A payment of over $22,450. Asfora billed Medicare for his professional services and received a Medicare Part B payment of over $795. SFSH paid MDLLC over $10,750 for the Samba products used in the surgery.

229. In early 2013, Asfora and MDLLC began discussions with medical device company Orthofix about entering into a license agreement relating to the Samba products. In May 2013, two months after OIG's special fraud alert on PODs, Asfora described to Orthofix "[t]he reason I want to sell" the rights to Samba products. Asfora claimed the reason "is not financial," noting that "there is great scrutiny of companies owned by physicians" and "I am just tired of all the BS involved."

230. Asfora said he believed Orthofix would allow MDLLC to "sell directly to my hospital if I am the user," and asked Orthofix "what would your offer be" if Orthofix sold to "my hospitals (Sanford and Sioux Falls Specialty Hospital)." Asfora noted that MDLLC had "billed for 50 SI joint fusions this year so far" and approximately $12,000 "is billed per [SI fusion] procedure including the implant and disposable pins and plunger for bone insertion."

231. In response, Orthofix warned Asfora on May 26, 2013: "I just want to be very clear that we would not be able to pay you royalties for any devices you personally use. Our company policy is based on anti-kickback rules that govern these types of transactions."

232. The next day, May 27, 2013, Asfora responded to Orthofix: "I agree fully and understand about inability to pay royalty for any product I use due to potential regulatory conflicts, and I certainly do not want to go down that path either."

233. Effective August 27, 2013, Orthofix and MDLLC entered into exclusive license and distribution agreements, which Asfora signed on behalf of MDLLC.

234. In the license agreement, MDLLC granted to Orthofix "an exclusive license to make, use, sell, offer for sale, import, export, and distribute" the Samba products. Orthofix agreed to pay MDLLC an initial fee of two million dollars, make a milestone payment after a certain amount of sales, and pay a royalty of six percent on certain sales. However, Orthofix refused to pay MDLLC royalties on Orthofix's sales of Samba products for Asfora's use or to count such sales when determining whether the milestone had been met.

235. The distribution agreement allowed Orthofix a ramp up period before it began distributing the Samba products. "During the ramp up period," the agreement allowed MDLLC "to utilize any existing inventory in the course of conducting any surgical procedures scheduled by any owner or employee of [MDLLC] prior to the Effective Date up until Orthofix commences distribution." The distribution agreement also included an exhibit listing the cost of the Samba products; those costs are listed in paragraphs 221 and 223, *supra*.

236. On November 7, 2013, Orthofix employees attended surgery with Asfora at SMC to mark the date when Orthofix commenced distribution of the Samba products. Orthofix notified MDLLC and Asfora in writing that the surgery was "the first official Orthofix Samba screw case."

Two weeks later, an MDLLC consultant emailed Orthofix, copying Asfora, providing a quote from Asfora, on behalf of MDLLC, for Orthofix to use in a press release: "We are delighted to have the sales and marketing power of Orthofix behind the global distribution of the Samba Screw."

237. Less than a year later, in late September 2014, MDLLC and Asfora sought to renegotiate the Orthofix agreements to allow MDLLC to distribute the Samba products for Asfora's use. MDLLC and Asfora made this request so that they, rather than Orthofix, could capture the profits from Asfora's use of the Samba products. On October 7, 2014, Orthofix again confirmed to Asfora in writing that "Orthofix is not willing to authorize [MDLLC] to distribute the Samba Screw System."

238. Despite the rejection, MDLLC and Asfora continued to complain to Orthofix about low royalty payments for Samba, noting in May 2015 that they had "no hope" that Orthofix would be successful. MDLLC and Asfora continued to ask Orthofix to "allow [MDLLC] to also promote and sell the Samba," and Orthofix continued to deny their requests.

239. For example, on May 16, 2015, Asfora asked Orthofix's CEO to allow MDLLC to "take over just my practice." Asfora explained, "[t]he way I am proposing I am also motivated to market my own practice and do more SI joint fusions."

240. Orthofix's CEO responded on the same day, warning Asfora: "Regarding your proposal, I will be very direct with you on this. It is illegal." Orthofix's CEO advised Asfora, "you will have a compliance issue selling Samba to your hospital whether you get a royalty or not. You need to be very careful and become educated about all the compliance laws that apply to you."

241. Despite this warning, MDLLC and Asfora continued to complain to Orthofix's CEO about the amount of royalties paid by Orthofix and continued to propose that MDLLC sell the Samba products. For example, in August 2015, Asfora told Orthofix's CEO that "[t]he royalty

check that I just received express[es] how poorly Orthofix has done," and Asfora offered to "buy all your inventory" of Samba products.

242. In October 2015, MDLLC and Asfora again proposed to Orthofix to allow MDLLC to distribute the Samba products. Orthofix again rejected the request, stating on October 26, 2015: "It does not work for Orthofix under any circumstances to have [MDLLC] sell the products directly."

243. In December 2015, MDLLC and Asfora again told Orthofix's CEO, "we should negotiate the Samba back to [MDLLC]." Orthofix continued to reject the requests.

244. Orthofix's repeated rejections and warnings did not deter MDLLC and Asfora from their plan to profit from Asfora's use of the Samba products. From November 2013 through January 2017, MDLLC sold the Samba products to SFSH for Asfora's use. From October 2016 through April 2017, MDLLC sold the Samba (and Bullet Cage) products at a profit to IMS to resell to SFSH for Asfora's use. After November 7, 2013, MDLLC received over $500,000 from its direct and indirect sales of Samba products to SFSH and distributed profits from such sales to Asfora and his wife.

245. MDLLC's sales of the Samba products to SFSH after November 7, 2013 violated MDLLC's agreements with Orthofix. Neither MDLLC nor Asfora ever disclosed such sales to Orthofix. Asfora and MDLLC hid from Orthofix each Samba sale by MDLLC after November 7, 2013 because they knew that Orthofix, if informed of the sales, would prevent MDLLC and Asfora from profiting from Asfora's use of the Samba products.

246. For example, on or about [redacted], 2014, Asfora implanted three Bullet Cages, three Samba screws, four Aegis pedicle screws, four Aegis set screws, and one Aegis curved rod in patient [redacted] (DOB [redacted]/1953) at SFSH, using three sharp Steinmann pins, one

long blunt Steinmann pin, one short blunt Steinmann pin, three drill bits, and one packing tube. SFSH billed TRICARE for the inpatient services and received a TRICARE payment of over $29,100. Asfora billed TRICARE for his professional services and received a payment of over $6,800. For the products used in the surgery, MDLLC received $12,000 for the Bullet Cages, over $14,250 for the Samba products, and over $2,250 for the Aegis products, for a total of over $28,500.

247. On or about [redacted] 2014, Asfora implanted three additional Samba screws in the same patient at SFSH, using three sharp Steinmann pins, one long blunt Steinmann pin, one short blunt Steinmann pin, three drill bits, and one packing tube. SFSH billed TRICARE for the inpatient services and received a TRICARE payment of over $11,370. Asfora billed TRICARE for his professional services and received a payment of over $1,500. SFSH paid MDLLC over $14,250 for the Samba products used in the surgery.

248. As another example, on or about [redacted] 2016, Asfora implanted five Samba screws in patient [redacted] (DOB [redacted] 1963) at SFSH, using three sharp Steinmann pins, one long blunt Steinmann pin, one short blunt Steinmann pin, three drill bits, and one packing tube. SFSH billed Medicare for the inpatient services and received a Medicare Part A payment of over $9,050. Asfora billed Medicare for his professional services and received a Medicare Part B payment of over $800. SFSH paid MDLLC over $21,250 for the Samba products used in the surgery.

249. As another example, on or about [redacted] 2016, Asfora implanted six Samba screws in patient [redacted] (DOB [redacted]/1976) at SFSH, using three sharp Steinmann pins, one long blunt Steinmann pin, one short blunt Steinmann pin, three drill bits, and one packing tube. SFSH billed Medicare for the inpatient services and received a Medicare Part A payment of over $9,050.

Asfora billed Medicare for his professional services and received a Medicare Part B payment of over $780. SFSH paid MDLLC over $24,750 for the Samba products that Asfora implanted in the surgery.

250. From November 2013 through April 2017, including in the representative examples above, there was no difference between the Samba products that Asfora used (from MDLLC) and the Samba products sold by the exclusive distributor (Orthofix). However, there was a difference in who would profit from Asfora's use of those products. In order to profit from his device use, Asfora chose to use in his surgeries at SFSH the Samba products distributed by MDLLC.

**F. Sicage Products**

251. In addition to covertly selling Samba products to SFSH to profit on Asfora's use of those products, MDLLC and Asfora developed a plan to profit from Asfora's use of SI screw products at Sanford.

252. To hide the true nature of their conduct from Sanford and Orthofix, Asfora and MDLLC employees created a new company—Sicage—and used that company to sell to Sanford for Asfora's use the Sicage screw system, which included the Sicage screw, Steinmann pins, drill bits, and packing tube (collectively, Sicage products).

253. The Sicage screw was substantially equivalent to the Samba screw. Aware that MDLLC had represented to the FDA in 2012 that the Samba screw was equivalent to the Synthes 6.5mm cannulated screw, Sicage represented to the FDA in 2017 that the Sicage screw was equivalent to the same Synthes screw.

254. MDLLC and Sicage had the same employees, same physician-owner, and were operated out of the same street address, in neighboring suites. MDLLC previously occupied Sicage's suite, and both MDLLC's and Sicage's suites were rented from an Asfora-owned entity.

255. In communications with colleagues, Asfora admitted his plan for Sicage. In an email with one colleague, for example, Asfora complained that Orthofix was manufacturing its own Samba devices and "will not buy the Samba" from MDLLC. Noting that "I am not going to lose all the Samba" in MDLLC's inventory, Asfora told his colleague, "let's do business with [MDLLC] for now," a reference to MDLLC's covert sales of Samba products in violation of the Orthofix agreements. For the future, Asfora told his colleague that "all contracts will be with the Sicage company." Asfora warned his colleague to "[k]eep it as quiet as possible."

256. Further, in an email to a Sanford employee who was assisting with Sicage, Asfora referenced their Sicage work and stated that "if this is successful we [will] all be rich and famous although I am only interested in the former and not that much."

257. From January 2018 to December 2018, Sicage offered to Asfora, and Asfora solicited from Sicage, profit distributions based on Asfora's use of Sicage products at SMC. For Asfora's surgeries using Sicage products, SMC paid Sicage $3,250 per Sicage screw, $595 per drill bit, $630 per packing tube, $84 per long blunt Steinmann pin, $70 per short blunt Steinmann pin, and $53 per sharp Steinmann pin.

258. For example, on or about [redacted] 2018, Asfora implanted three Sicage screws in patient [redacted] (DOB [redacted]1943) at SMC, using one long blunt Steinmann pin, one packing tube, and three drill bits. SMC billed Medicare and TRICARE for the inpatient services and received a Medicare Part A payment of over $25,250 and a TRICARE payment of over $1,300. Asfora billed Medicare and TRICARE for his professional services and received a Medicare Part B payment of over $500 and a TRICARE payment of over $125. SMC paid Sicage over $12,200 for the Sicage products Asfora used in the surgery.

259. Less than [redacted] days later, Asfora implanted six additional Sicage screws in the same patient at SMC, using six drill bits and two packing tubes. SMC billed Medicare and TRICARE for the inpatient services and received a Medicare Part A payment of over $25,800 and a TRICARE payment of over $1,300. Asfora billed Medicare and TRICARE for his professional services and received a Medicare Part B payment of over $500 and a TRICARE payment of over $125. SMC paid Sicage over $24,300 for the Sicage products used in the surgery.

260. As another example, on or about [redacted], 2018, Asfora implanted eight Sicage screws in patient [redacted] (DOB [redacted]/1980) at SMC, using two sharp Steinmann pins, two drill bits, and two packing tubes. SMC billed Medicaid for the inpatient services and received a Medicaid payment of over $21,700. SMC paid Sicage over $28,500 for the Sicage products Asfora used in the surgery.

## II. ADDITIONAL WARNINGS TO ASFORA OF UNNECESSARY PROCEDURES

### A. Sanford Warned Asfora that He Was a High-Risk Physician

261. After receiving an unusually high number of patient complaints about Asfora compared to his peers, Sanford warned Asfora that his practice was riskier than that of his peers.

262. Since at least 2008, Sanford Health used Vanderbilt University's Patient Advocacy Reporting System (PARS) to systematically identify patterns of patient dissatisfaction. Patient dissatisfaction, Sanford Health advised Asfora, "undermines patient adherence with medical treatment plans, outcomes of care, and patients' willingness to stay with a practice." As part of the PARS program, Vanderbilt calculated risk scores for every Sanford Clinic physician, including Asfora, and compared them to local and national peer group scores.

263. Each reporting year, Sanford provided Asfora with a report summarizing his PARS risk score, explaining the PARS methodology, and attaching documentation supporting his risk score.

264. Not only was Asfora a high-risk physician when Sanford began the PARS program, Asfora's risk score more than doubled from 2008 to 2017. As Asfora expanded his use of products in which he had a financial interest, patient complaints about him soared, putting him in the riskiest category measured by the national PARS data.

265. In October 2012, Sanford informed Asfora that of the 5,500+ surgeons in the national PARS database, Asfora's "risk score stood out within the highest tier; specifically, it was higher than that of 90% of all surgeons in the national PARS database." From August 2008 to August 2012, Asfora's "Risk Score of 60 [was] within top 3% of All Physicians and #33 of 294 Neurosurgeons in the National PARS database."

266. In October 2013, Sanford informed Asfora that from August 2009 to August 2013, his "Risk Score of 92 [was] within top 1% of All Physicians and #14 of 336 Neurosurgeons in the National PARS Database."

267. In November 2014, Sanford advised Asfora that from August 2010 to August 2014, his "Risk Score of 108 [was] within top 0.5% of All Physicians" and "#12 of 270 Neurosurgeons" in the National PARS Database.

268. In October 2015, Sanford advised Asfora that from August 2011 to August 2015, his "Risk Score of 118 [was] within top 0.5% of All Physicians" and "#7 of 279 Neurosurgeons" in the National PARS Database.

269. In October 2016, Sanford told Asfora that from August 2012 to August 2016, his "Risk Score of 129 [was] within top 0.5% of All Physicians" and "#5 of 310 Neurosurgeons" in the National PARS Database.

270. In September 2017, Sanford told Asfora that from July 2016 to June 2017, his risk score of 102 was within the top 0.5% of all physicians and "#6 of 378 Neurosurgeons" in the National PARS Database.

271. Despite Asfora's very high risk score, Asfora did not change his clinical practice. Rather, during that period, Asfora participated in new kickback schemes and continued to submit, and cause the Hospitals to submit, claims for the resulting services to federal healthcare programs.

**B. Sanford Surgical Committee Warned Asfora of Excessive Fusion**

272. In [redacted] 2011, Asfora performed a five-level fusion at SMC, implanting in the patient five Bullet Cages, for which SMC paid MDLLC over $19,000. The patient subsequently suffered paraparesis (partial paralysis of the lower limbs).

273. In [redacted] 2011, Asfora's surgery was referred to Sanford Health's Surgery Case Review committee to review. In [redacted] 2012, at least eight Sanford Clinic physicians, including two neurosurgeons, met to review the surgery. After reviewing the medical records and considering Asfora's explanation for the surgery, Sanford Health's Surgery Case Review committee concluded that the patient's "paraparesis of both lower limbs" was "related to the length of the surgery" and that "this was an aggressive procedure in this situation." The committee found that Asfora had "vari[ed] from accepted standard of care" by "subjecting the patient to an extremely lengthy complex procedure when a shorter procedure could have been used." The committee then requested that Sanford Health review "extensive surgical procedures (adult multi level)" at SMC.

274. By letter, Sanford Health informed Asfora of the committee's findings, writing that the committee had "assigned a Category III Standard of Care" to the procedure, based on "subjecting the patient to an extremely complex procedure which may have been managed more

conservatively." Sanford advised Asfora that it believed his procedure was a "variation in standard of care."

### C. Sanford External Peer Reviewer Warned of Asfora's Excessive Fusion

275. As requested by its Surgery Case Review committee, Sanford Health began a review of Asfora's multi-level spinal procedures. Sanford Health retained the American Medical Foundation for Peer Review (AMF) to provide "an outside unbiased review" of Asfora's surgeries. In September 2013, Sanford Health sent to AMF the medical records for one patient: [redacted] (DOB [redacted]/1955), on whom Asfora had performed a four-level cervical discectomy and fusion at SMC on or about [redacted] 2012. Sanford Health asked AMF to provide "a written summary report" of "whether or not the patient's management met current standard of care based upon your reviewer's expert clinical opinion." Sanford Health explained to AMF that "the nature of the concern relates to surgical indication for the performance of multi-level spine procedures" by "one provider [Asfora]."

276. On or about December 3, 2013, Sanford Health received the independent peer review report of Asfora's surgery on patient [redacted]. Sanford shared the report with Asfora.

277. The reviewer, a board-certified member of the American Board of Neurological Surgeons and professor of neurological and orthopedic surgery, reported that the patient "presented with no signs or symptoms of neurologic dysfunction and had a normal EMG with no evidence of myelopathy."

278. The reviewer stated that he was "unsure why Dr. Asfora proceeded with multiple-level discectomy, in that the clear pathology based on her imaging studies are at the C5–C6 and C6–C7 levels." The two additional levels on which Asfora performed surgery, the reviewer explained, "go against conventional neurosurgical teaching and practice."

279. The reviewer warned that Asfora had "treated quite aggressively" the patient. Because there was "no evidence of myelopathy or neurologic dysfunction," many surgeons would not have performed any spinal fusion surgery on the patient. Even if surgical intervention was contemplated, then based on the patient's "imaging and clinical symptomatology," Asfora's fusion of two additional spinal levels was "excessive."

280. The reviewer warned that such excessive spinal fusion surgeries could—and in this case did—cause patient harm. The reviewer explained that Asfora's surgery was "particularly troublesome in that surgical treatment at the superior levels of the spine often lead to increasing swallowing dysfunctions as was witnessed in this patient." Asfora's additional, excessive levels of spinal fusion also caused an "increase in operative time as well as loss of range of motion," which the reviewer found "does not seem to be justified."

281. Asfora used a Life Spine cervical plate in the four-level spinal fusion of this patient. At the time of the patient's surgery in [redacted] 2012, Asfora believed that MDLLC would be reselling at a profit such Life Spine products to Sanford Health. MDLLC had billed Sanford Health for Life Spine cervical plates just [redacted] days before the patient's surgery. Only after the patient's procedure did MDLLC learn that Sanford Health would not pay MDLLC for the Life Spine products.

### D. Second Sanford External Peer Reviewer Warned of Asfora's Excessive Fusions

282. On December 9, 2014, a Sanford Clinic physician submitted to Sanford Health and SMC a written review of Asfora's [redacted] 2014 surgery on patient [redacted] (DOB [redacted]/1942), a Medicare beneficiary. The reviewing physician noted that Asfora had performed a "[w]rong site surgery," which Asfora had "[f]ail[ed] to identify" during the surgery, and which Asfora had "[f]ail[ed] to document correctly [after being] notified of [the] wrong site surgery by [a] colleague." Asfora had implanted numerous Aegis products in this surgery.

283. No defendant disclosed to any federal healthcare program that a Sanford Clinic physician had determined in December 2014 that Asfora had performed a "wrong site surgery" or otherwise performed more extensive surgery on [redacted] than was medically necessary. Indeed, no defendant disclosed to any federal healthcare program the Sanford Clinic physician's December 2014 written review, any portion of the review, or any finding or conclusion in the review.

284. About six months later, a Sanford Clinic physician submitted another review to Sanford Health and SMC for Asfora's surgery on patient [redacted] (DOB [redacted] 1952). Asfora had performed the surgery on or about [redacted] 2014 at SMC. The physician noted that Asfora had performed another "wrong site surgery"—"2nd time in 6 mo[nths] for this provider." Asfora had implanted numerous Aegis products in this surgery.

285. On or about September 2, 2015, Sanford Health sent the medical records for Asfora's [redacted] and [redacted] surgeries to AMF for an independent external review of "whether or not the patient's management met current standard of care based upon your reviewers' expert clinical opinion." Less than a month later, Sanford Health received the external peer review report from AMF for the two procedures. Again, Sanford Health shared the report with Asfora.

286. The independent review of the two cases was conducted by a board-certified member of the American Board of Neurological Surgeons and professor of neurosurgery and orthopaedics. The first case concerned a three-level anterior cervical discectomy and fusion (ACDF) that Asfora performed on patient [redacted]. The reviewer concluded that a "single level" fusion "would be a reasonable and common recommendation" for the patient. Although the reviewer noted that many spine surgeons would include a second level in the spinal fusion surgery, the third level—which Asfora also included—was "near normal on MRI." The reviewer concluded, "[i]t is unclear to me why the third level was added," and Asfora documented no reason

to support fusing the third level "other than he decided to add the level and he obtained consent from the wife."

287. The second case described in the reviewer's September 2015 report concerned a four-level ACDF that Asfora performed on patient [redacted]. After reviewing the medical records, the reviewer concluded that "[a]ll imaging findings are age appropriate" for a patient over [redacted] years old. Nevertheless, Asfora chose to perform a four-level fusion on the patient. As the reviewer noted, "[f]our-level ACDF are rare surgeries performed in a patient without spinal cord compression at all fusion levels." The patient, the reviewer explained, "had mostly neck pain and arm pain which could have been addressed with fewer levels included in the surgery."

288. In the surgery, "several screws [were] placed suboptimally" by Asfora. Further, Asfora did "not document[] in any of the paperwork associated with surgery or post-op care" why he had extended the fusion into the upper thoracic spine. Such fusions, the reviewer noted, "can be dangerous" and "rarely" are performed, particularly in "degenerative spine cases" like patient [redacted]. In conclusion, the reviewer warned: "In an academic medical center with peer review from other spine surgeons, such a case would qualify for a morbidity and mortality discussion."

289. In or about [redacted] 2014, SMC submitted a claim to Medicare Part A for patient [redacted]'s surgery, and Asfora submitted a claim to Medicare Part B for his professional services in the surgery. Medicare paid SMC over $13,300 for its Part A claim, and Medicare paid Asfora over $2,750 for his Part B claim.

290. No defendant disclosed to any federal healthcare program that an external independent reviewer had determined in September 2015 that Asfora had performed a more extensive surgery on [redacted] than was medically necessary. Indeed, no defendant disclosed to

any federal healthcare program the independent external reviewer's September 2015 report, any portion of the report, or any finding or conclusion in the report.

## III. DEFENDANTS' ADDITIONAL FALSE STATEMENTS TO SANFORD

291. From 2013 to 2018, Sanford Health required Asfora to submit completed conflict of interest forms on at least an annual basis. Before submitting the forms, Asfora was required to acknowledge that he had "read and underst[oo]d the [Sanford] Financial Conflicts of Interest Policy." That policy required certain employees such as Asfora to disclose specified financial interests "[a]t least annually" and "within 30 days of discovering or acquiring . . . a new conflict of interest." With respect to privately-held entities like MDLLC and Sicage, Sanford advised Asfora that "a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the [physician] (or the [physician's] spouse or dependent children) holds any equity interest" in such entity.

292. The conflict of interest forms required Asfora to disclose to Sanford certain financial relationships. To make clear that Sanford was relying on the accuracy of Asfora's responses, the forms required Asfora to certify that "the information provided is to the best of my knowledge true and complete and does not misstate any facts."

293. Each year from 2013 to 2018, Asfora submitted such conflict of interest forms to Sanford, sometimes multiple times per year. In each such submission, Asfora misrepresented his financial arrangements with MDLLC, Sicage, or both.

294. On or about August 13, 2013, Asfora submitted a conflict of interest form to Sanford. That form advised Asfora, in bold text, "You need to disclose any financial relationship with an external company or organization where you or an immediate family member received remuneration or if you hold equity in said company." Asfora listed MDLLC on the form, but

represented that the "total value" of his and his wife's equity interests in the company was "$0.00." Asfora affirmed that "the information provided is to the best of my knowledge true and complete and does not misstate any facts." Asfora submitted additional conflict of interest forms on or about February 9, 2015 and June 28, 2015, confirming the above-referenced answers and affirmation contained in the August 13, 2013 submission.

295. On or about February 10, 2014, Asfora submitted another conflict of interest form to Sanford. Again, that form advised Asfora, "You need to disclose any financial relationship with an external company or organization where you or an immediate family member received remuneration or if you hold equity in said company." Asfora listed MDLLC on the form, but represented that the "total value" of his and his wife's equity interests in the company was "$0.00." With respect to the Samba products, Asfora represented to Sanford that his contract with Orthofix "specifically states that I an [sic] not to receive any compensation for any SambaScrew which I might utilize," and Asfora confirmed, "I do not receive compensation for any SambaScrews utilized in my medical practice." Asfora affirmed that "the information provided is to the best of my knowledge true and complete and does not misstate any facts." Asfora submitted additional conflict of interest forms on or about November 4, 2015, June 2, 2016, June 6, 2017, October 5, 2017, June 10, 2018, and May 15, 2019 confirming the above-referenced answers and affirmation contained in the February 10, 2014 submission.

296. From 2013 through 2018, Asfora failed to disclose to Sanford in his conflict of interest submissions both the amounts of money that MDLLC paid Asfora and his wife and Asfora's equity interest in Sicage. *See, e.g.*, *supra* ¶ 142.

## IV. MDLLC'S AND SICAGE'S ADDITIONAL FALSE STATEMENTS TO THE UNITED STATES

### A. Congress Required Applicable Manufacturers to Disclose Information to HHS on Physician Ownership and Payments

297. Concerned that physicians' treatment decisions could be affected by their financial interests, Congress enacted in 2010 a national disclosure program relating to such financial interests. 42 U.S.C. § 1320a-7h. Initially, it was referred to as the Physician Payment Sunshine Act (or Sunshine Act), but the disclosure program is now known as the Open Payments program.

298. All manufacturers operating in the United States and "engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply" must report certain information about physician payments and ownership interests. 42 U.S.C. § 1320a-7h(e)(9). As HHS has indicated, "an entity that holds an FDA approval, licensure, or clearance for a covered product" is "clearly 'engaged in the production, preparation, propagation, compounding, or conversion' of a covered product." 78 Fed. Reg. 9458, 9462 (Feb. 8, 2013). Likewise, entities "that hold the title to a covered drug, device, biological or medical supply meet the definition of an applicable manufacturer." *Id.* at 9461.

299. Pursuant to the Open Payments program, "any applicable manufacturer that provides a payment or other transfer of value" to a physician is required to report to HHS information about the payment or transfer, unless a reporting exclusion applies. 42 U.S.C. § 1320a-7h(a)(1)(A). For each qualifying payment or other transfer of value to a physician, an applicable manufacturer must report to HHS, among other things, the physician's name, business address, specialty, and National Provider Identifier (NPI); the amount of the payment or transfer; the date(s) on which the payment or transfer was provided; and descriptions of the form and nature of the payment or transfer. *Id.*

300. In addition, applicable manufacturers are required to report to HHS information about "any ownership or investment interest" in the manufacturer held by a physician or immediate family member, including a spouse, except for certain interests in publicly-traded security and mutual funds. 42 U.S.C. § 1320a-7h(a)(2). An applicable manufacturer must report to HHS, among other things, the physician's name, business address, specialty, and NPI; the dollar amount invested by the physician; the value and terms of each ownership or investment interest; and any payment or other transfer of value provided to a physician holding such interest. *Id.*

301. Applicable manufacturers are required to report the specified information on the 90th day of each calendar year, for payments and ownership interests in the preceding calendar year. 42 U.S.C. § 1320a-7h(a)(1)(A). The first reporting deadline was March 31, 2014, for calendar year 2013. 42 C.F.R. § 403.908(a).

302. Under the Open Payments program, HHS makes certain information about the payments and ownership interests available to the public through a searchable website. 42 U.S.C. § 1320a-7h(c)(1)(C); *see also* https://www.cms.gov/openpayments (last visited Nov. 13, 2019).

303. Applicable manufacturers are subject to civil monetary penalties for failing to timely submit information required by the Open Payments program, and are subject to additional penalties for knowing (including reckless) failures to timely submit required information. 42 U.S.C. § 1320a-7h(b)(1)–(2). For violations occurring on or before November 1, 2015, civil penalties of up to $1,000,000 may be imposed for knowing violations, and an additional $150,000 per year may be imposed regardless of whether the failure was knowing. *Id.* For violations occurring after November 1, 2015, civil penalties of up to $1,127,799 may be imposed for knowing violations, and an additional $169,170 per year may be imposed regardless of whether the failure was knowing. 83 Fed. Reg. 51,369, 51,379 (Oct. 11, 2018).

### B. MDLLC and Sicage Failed to Disclose Required Information to HHS on Physician Ownership and Payments

304. From 2013 through 2018, MDLLC was operating in the United States, had received FDA clearance for medical devices, including the Bullet Cage device, and held title to and distributed that device. MDLLC never has been publicly traded.

305. For calendar years 2013 through 2018, MDLLC failed to disclose to HHS any physician payments or ownership interests by the required deadlines. By the March 31, 2018 deadline for the 2017 calendar year submission, MDLLC had not even registered to submit the required information to HHS, much less submitted any such information to HHS. Although MDLLC registered with HHS in September 2018 to submit information required by the Open Payment program, MDLLC did not submit any such information by the March 31, 2019 deadline for the 2018 calendar year.

306. From 2017 to 2018, Sicage was operating in the United States, had received FDA clearance for the Sicage device, and held title to and distributed that device. Sicage never has been publicly traded.

307. For calendar years 2017 and 2018, Sicage failed to disclose to HHS any physician payments or ownership interests by the required deadlines. By the March 31, 2019 deadline for the 2018 calendar year submission, Sicage had not even registered to submit the required information to HHS, much less submitted any such information to HHS.

308. On April 17, 2019, MDLLC was served with a civil investigative demand from the United States Department of Justice, seeking, among other things, interrogatory answers regarding "each physician and spouse of a physician who has held an investment or ownership interest in [MDLLC]" and MDLLC's "payments of money or other items of value directly or indirectly to the physician or spouse." One week later, MDLLC reported to the Open Payments program certain

information about Asfora's and his wife's ownership interests in MDLLC. However, in that and later Open Payments reporting, MDLLC did not disclose any of its payments or transfers of value to Asfora, even though MDLLC paid Asfora hundreds of thousands of dollars from 2013 to 2018. *See, e.g.*, *supra* ¶ 142. Sicage also did not disclose to the Open Payments program any ownership interest by Asfora.

### C. MDLLC and Sicage Knowingly Failed to Disclose the Required Information to HHS

309. In late July 2013, before reporting began in the first year of the Open Payments program, an MDLLC employee, Kelly Spielman, asked an outside vendor for "any examples of a Form that Lifespine or Orthofix might use to keep track of physician payments." Spielman admitted: "We need to have some kind of procedure and form for tracking this information in compliance with the Sunshine Act."

310. The following month, Sanford reminded Asfora by email about "federal compliance and the new 'Sunshine Act.'" Asfora responded to the email on the day it was sent, acknowledging receipt.

311. The same month, the Congress of Neurological Surgeons (CNS) emailed Asfora, advising him that "Sunshine Act reporting has begun." CNS further noted: "Under the Sunshine Act, manufacturers of drugs, medical devices, and biologics must submit annual reports to the CMS outlining certain payments and items of value given to physicians and teaching hospitals. In addition, manufacturers and group purchasing organizations (GPOs) must report certain ownership interests held by physicians and their immediate family members. Reportable transactions include direct and indirect payments and transfers of value, as well as payments and transfers of value that are made to a third-party at the request of or on behalf of a physician."

312. Spielman testified that she and Kristi Vondra, MDLLC's VP of Operations, had drafted a standard operating procedure (SOP) to comply with the Sunshine Act. In order for an SOP regarding the Sunshine Act to be put into place at MDLLC, Asfora would have had to approve it. That SOP, however, was not approved.

313. In 2016, SFSH notified Asfora in writing that he should "be aware that under the Physician Payments Sunshine Act, all payments or transfers of value that exceed $10 (or that exceed $100 in annual aggregate) made by a Vendor or manufacturer of a medical drug, device, piece of equipment, or other product to a physician must be reported." Asfora signed and dated the document in June 2016 and provided it to the hospital.

314. Despite their knowledge of the Open Payments program and its reporting requirements, MDLLC and Sicage—as well as Asfora (an owner of MDLLC and Sicage) and Vondra and Spielman (MDLLC's and Sicage's only employees from 2013 to 2018)—did not report to the Open Payments program any payments from MDLLC or Sicage to Asfora, and did not timely report Asfora's ownership interests in those companies.

**COUNT I**
**(Against Asfora and MDLLC)**
**False Claims Act, 31 U.S.C. § 3729(a)(1)(A)**
**Presenting and Causing False Claims to Be Presented for Payment**

315. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

316. Asfora knowingly submitted, and knowingly caused the Hospitals to submit, claims for payment to Medicare, Medicaid, and TRICARE for surgeries and related services that were false or fraudulent, and not payable, because Asfora knowingly and willfully solicited and received remuneration in violation of the AKS to induce him to order, arrange for, and recommend the

purchase of MDLLC, Life Spine, Aegis, and Samba products for which payment was made in whole or in part by Medicare, Medicaid, and TRICARE.

317. MDLLC knowingly caused Asfora, SMC, and SFSH to submit claims for payment to Medicare, Medicaid, and TRICARE for surgeries and related services that were false or fraudulent, and not payable, because MDLLC knowingly and willfully offered and paid remuneration to Asfora in violation of the AKS to induce Asfora to order, arrange for, and recommend the purchase of MDLLC, Life Spine, Aegis, and Samba products for which payment was made in whole or in part by Medicare, Medicaid, and TRICARE.

318. In addition to and independent of the above-referenced AKS violations, Asfora knowingly submitted, Asfora caused the Hospitals to submit, and MDLLC caused Asfora, SMC, and SFSH to submit claims for payment to Medicare, Medicaid, and TRICARE that were not payable, and were false and fraudulent because certain of Asfora's spinal surgeries and related professional services using MDLLC, Life Spine, Aegis, and Samba products were not medically necessary or were more extensive than necessary. Asfora and MDLLC knew that MDLLC's payments to Asfora caused Asfora to perform, and Asfora and the Hospitals to submit claims to Medicare, Medicaid, and TRICARE for, surgeries and related services using MDLLC, Life Spine, Aegis, and Samba products that were not medically necessary or were more extensive than was necessary.

319. By virtue of these false or fraudulent claims, the United States suffered damages in an amount to be determined at trial.

**COUNT II**
**(Against Asfora and Sicage)**
**False Claims Act, 31 U.S.C. § 3729(a)(1)(A)**
**Presenting and Causing False Claims to Be Presented for Payment**

320. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

321. Asfora submitted, and knowingly caused SMC to submit, claims for payment to Medicare, Medicaid, and TRICARE for surgeries and related services that were false or fraudulent, and not payable, because Asfora knowingly and willfully solicited and/or received remuneration in violation of the AKS to induce him to order, arrange for, and recommend the purchase of Sicage products for which payment was made in whole or in part by Medicare, Medicaid, and TRICARE.

322. Sicage knowingly caused Asfora and SMC to submit claims for payment to Medicare, Medicaid, and TRICARE for surgeries and related services that were false or fraudulent, and not payable, because Sicage knowingly and willfully offered and/or paid remuneration to Asfora in violation of the AKS to induce Asfora to order, arrange for, and recommend the purchase of Sicage products for which payment was made in whole or in part by Medicare, Medicaid, and TRICARE.

323. In addition to and independent of the above-referenced AKS violations, Asfora knowingly submitted, Asfora caused SMC to submit, and Sicage caused Asfora and SMC to submit claims for payment to Medicare, Medicaid, and TRICARE that were not payable, and were false and fraudulent because certain of Asfora's spinal surgeries and related professional services using Sicage products were not medically necessary or were more extensive than necessary. Asfora and Sicage knew that the payments Asfora solicited from Sicage caused Asfora to perform, and Asfora and SMC to submit claims to Medicare, Medicaid, and TRICARE for, surgeries and

related services using Sicage products that were not medically necessary or were more extensive than was necessary.

324. By virtue of these false or fraudulent claims, the United States suffered damages in an amount to be determined at trial.

**COUNT III**
**(Against Asfora and MDLLC)**
**False Claims Act, 31 U.S.C. § 3729(a)(1)(B)**
**Use of False Statements**

325. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

326. During the relevant time period, Asfora and MDLLC knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims submitted to the United States, and payment of those false or fraudulent claims by the United States was a reasonable and foreseeable consequence of Asfora's and MDLLC's statements and actions.

327. These false records and statements included false certifications on provider enrollment forms and false and misleading representations on claim forms that the claims to Medicare, Medicaid, and TRICARE for Asfora's spinal surgeries using MDLLC, Life Spine, Aegis, and Samba products complied with the AKS and were for medically necessary services, when in fact those claims violated the AKS and/or were for medically unnecessary services.

328. Asfora and MDLLC made or used, or caused to be made or used, such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

329. By virtue of these false or fraudulent claims, the United States suffered damages in an amount to be determined at trial.

**COUNT IV**
**(Against Asfora and Sicage)**
**False Claims Act, 31 U.S.C. § 3729(a)(1)(B)**
**Use of False Statements**

330. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

331. During the relevant time period, Asfora and Sicage knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims submitted to the United States, and payment of those false or fraudulent claims by the United States was a reasonable and foreseeable consequence of Asfora's and Sicage's statements and actions.

332. These false records and statements included false certifications on provider enrollment forms and false and misleading representations on claim forms that the claims to Medicare, Medicaid, and TRICARE for Asfora's spinal surgeries using Sicage products complied with the AKS and were for medically necessary services, when in fact those claims violated the AKS and/or were for medically unnecessary services.

333. Asfora and Sicage made or used, or caused to be made or used, such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

334. By virtue of these false or fraudulent claims, the United States suffered damages in an amount to be determined at trial.

**COUNT V**
**(Against Asfora and MDLLC)**
**False Claims Act, 31 U.S.C. § 3729(a)(1)(C)**
**Conspiracy to Submit False Claims**

335. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

336. Asfora and MDLLC entered into an unlawful agreement to cause the presentation of false or fraudulent claims to the United States, and performed acts in furtherance of this conspiracy. Specifically, Asfora and MDLLC used MDLLC as a vehicle through which to offer and/or pay Asfora remuneration in order to induce him to use MDLLC, Life Spine, Aegis, and Samba products in his surgeries at the Hospitals.

337. MDLLC performed acts in furtherance of this conspiracy by, among other things, entering into arrangements to manufacture MDLLC and Samba products for Asfora's use; entering into arrangements to acquire Life Spine and Aegis products for Asfora's use; distributing MDLLC, Life Spine, Aegis, and Samba products to the Hospitals for Asfora's use; soliciting and receiving remuneration from Life Spine and Aegis; and paying Asfora to induce him to use such products.

338. Asfora performed acts in furtherance of this conspiracy by, among other things, soliciting and receiving remuneration from MDLLC, Life Spine, and Aegis; causing the Hospitals to order MDLLC, Life Spine, Aegis, and Samba products; using such products in his surgeries; and presenting and causing to be presented claims to Medicare, Medicaid, and TRICARE for such surgeries and hospital services.

339. By virtue of these false or fraudulent claims, the United States suffered damages in an amount to be determined at trial.

**COUNT VI**
**(Against Asfora and Sicage)**
**False Claims Act, 31 U.S.C. § 3729(a)(1)(C)**
**Conspiracy to Submit False Claims**

340. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

341. Asfora and Sicage entered into an unlawful agreement to cause the presentation of false or fraudulent claims to the United States, and performed acts in furtherance of this conspiracy.

Specifically, Asfora and Sicage used Sicage as a vehicle through which to offer and/or pay Asfora remuneration in order to induce him to use Sicage products in his surgeries at SMC.

342. Sicage performed acts in furtherance of this conspiracy by, among other things, entering into arrangements to manufacture Sicage products for Asfora's use; distributing Sicage products to SMC for Asfora's use; and offering and/or paying Asfora to induce him to use such products.

343. Asfora performed acts in furtherance of this conspiracy by, among other things, soliciting and/or receiving remuneration from Sicage; concealing his ownership in Sicage from Sanford and the United States; causing Sanford to order Sicage products for his use at SMC; using such products in his surgeries; and presenting and causing to be presented claims to Medicare, Medicaid, and TRICARE for such surgeries and hospital services.

344. By virtue of these false or fraudulent claims, the United States suffered damages in an amount to be determined at trial.

**COUNT VII**
**(Against All Defendants)**
**Unjust Enrichment**

345. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

346. This is a claim for the recovery of monies by which all defendants have been unjustly enriched.

347. By directly or indirectly obtaining from the United States, through Medicare, Medicaid, and TRICARE, funds to which they were not entitled, defendants were unjustly enriched, and are liable to account and pay such amounts, or the proceeds therefrom, which are to be determined at trial.

## COUNT VIII
**(Against All Defendants)**
**Payment by Mistake**

348. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

349. This is a claim for the recovery of monies the United States paid directly or indirectly to defendants as a result of mistaken understandings of fact.

350. The United States' mistaken understandings of fact were material to its decision to pay the claims submitted by Asfora and the Hospitals for surgeries Asfora performed using MDLLC, Life Spine, Aegis, Samba, and Sicage products and for related services.

351. The United States, acting in reasonable reliance on the truthfulness of the claims and the truthfulness of statements, certifications, and representations by Asfora and the Hospitals, paid monies directly or indirectly to defendants to which they were not entitled. Thus, the United States is entitled to recoup such monies, in an amount to be determined at trial.

## PRAYER FOR RELIEF

The United States requests that judgment be entered in its favor and against defendants as follows:

(a) On Counts I, II, III, IV, V, and VI (False Claims Act), for treble the United States' damages, together with the maximum civil penalties allowed by law;

(b) On Count VII (Unjust Enrichment), in the amount by which defendants were unjustly enriched;

(c) On Count VIII (Payment By Mistake), in the amount illegally obtained and retained by defendants; and

(d) Pre- and post-judgment interest, costs, and such other relief as the Court may deem appropriate.

## JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, the United States requests a trial by jury.

Date: November 13, 2019.

Respectfully Submitted,

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